UNITED STATES DISTRICT COURT
NORTHERN DISCTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
CASEY BRUBAKER and CATHY BRUBAKER husband and wife 19184 Quebec Avenue Corona, California 92881 Plaintiffs vs. ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC. Morris Corporate Center III 400 Interpace Parkway Parsippany, NJ 07054 Defendants	COMPLAINT AND JURY DEMAND Civil Action No:._____

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, Casey Brubaker and Cathy Brubaker, husband and wife, by and through their undersigned counsel hereby brings this civil action against Defendants, AbbVie Inc. and Abbott Laboratories, Inc. ["Defendants"] based upon the predicate facts and causes of action set forth below. Plaintiffs aver as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiffs, Casey Brubaker and Cathy Brubaker, husband and wife ["Plaintiff-husband" and "Plaintiff-wife" and jointly, "Plaintiffs"], are adult citizens and residents of

California, residing therein at 19184 Quebec Avenue, Corona, Riverside County, California 92881.

2. Defendant, Actavis, Inc. ["Actavis"], is a corporation organized according to and existing under the laws of the State of Nevada, with headquarters and a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. This Court has proper jurisdiction over Defendants and this civil action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy between Plaintiffs and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have and maintain significant contacts with this district by virtue of doing business within this judicial district.

4. Venue is proper within this district pursuant to Case Management Order No. 12 in MDL 2545 *In re: Testosterone Replacement Therapy Products Liability Litigation*, that permits any plaintiff whose case would be subject to transfer to MDL 2545 to file his or her case directly in the MDL Proceedings.

ALLEGATIONS GIVING RISE LIABILITY

5. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

6. Androderm is a testosterone transdermal system, a patch, that is designed to deliver testosterone continuously for 24 hours following application to intact, non-scrotal skin including the back, abdomen, thighs, and upper arms.

7. TheraTech, Inc. developed Androderm.

8. Androderm 2.5mg/24hour patch was originally approved by the FDA in September 1995.

9. SmithKline Beecham had exclusive marketing rights for Androderm in the United States from in or around 1995 until in or around May 1999.

10. On May 2, 1997, the FDA approved TheraTech, Inc.'s supplemental new drug application for marketing an additional 5mg/24 hour strength Androderm patch.

11. In January 1999, Watson Pharmaceuticals, Inc. ["Watson"] acquired TheraTech, Inc. as a wholly-owned subsidiary.

12. In May 1999, Watson Pharmaceuticals reacquired the U.S. and Canadian rights to the Androderm testosterone transdermal system from Glaxo SmithKline PLC, formerly SmithKline Beecham PLC.

13. In October, 2011 the FDA approved Androderm 2mg/24 hour and 4mg/24 hour formulations and the 2.5mg/24hour and 5mg/24 hour patches were discontinued..

14. On October 31, 2012, Watson completed the acquisition of the Actavis Group.

15. In January 2013, Watson changed its corporate name to "Actavis, Inc."

16. In or around October 1, 2013, Actavis became a wholly-owned subsidiary of Actavis plc, a limited public company incorporated in Ireland.

17. At all times material hereto, Androderm was sequentially a pharmaceutical product manufactured, distributed, marketed, sold, and promoted by Actavis and their predecessors-in-interest, and these companies successively assumed legal responsibility and liability for the design, regulatory approval, warnings, labelling, marketing and promotional content, safety and effectiveness, and manufacturing quality of the Androderm products.

18. The Androderm product was approved by the FDA in for the treatment of male primary and secondary hypogonadism.

19. The Androderm product reached the Plaintiff-husband, as a consumer and patient, from Actavis, and/or its predecessors-in-interest in an unaltered condition through the stream of interstate commerce.

20. Plaintiff-husband was within the market to which Actavis and/or its predecessors-in-interest directed its product marketing, physician-detailing, consumer and physician advertising and marketing, and promotional sales strategies and initiatives with respect to the Androderm product.

21. Actavis and/or its predecessors-in-interest undertook a duty to provide accurate, reliable, and truthful information to patients and consumers, including the Plaintiff-husband, concerning Androderm's safety and effectiveness profiles, clinical indications for use, and approved clinical uses.

22. At all times material hereto, Actavis and/or its predecessors-in-interest made no changes to the Androderm product labelling or Medication Guide to include the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

23. At all times material hereto neither Actavis and/or its predecessors-in-interest made labelling or Medication Guide changes, or offered information to consumers and patients, concerning the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

24. Hypogonadism is a medical disorder characterized by low testosterone levels caused by a congenital or acquired injury to or infection or pathological conditions of the male reproductive organs (testes); or pathologic conditions of the hormonal axis which regulates testosterone production by the male reproductive organs.

25. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men.

26. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders (e.g., space occupying lesions of the pituitary fossa) and other conditions which cause suppression of gonadotropin-releasing hormone [“GnRH”].

27. GnRH is a trophic peptide hormone responsible for the release of follicle-stimulating hormone [“FSH”] and luteinizing hormone [“LH”] from the anterior pituitary gland.

28. GnRH is synthesized and released from neurons within the hypothalamus.

29. In men, LH binds to receptors on Leydig cells in the testes, and stimulates the synthesis and secretion of testosterone.

30. In men, FSH is critical for sperm production.

31. FSH supports the function of Sertoli cells, which in turn support sperm cell maturation.

32. At all times material hereto, and since the time that the Androderm product was approved by the FDA, Actavis and/or its predecessors-in-interest knew and understood the FDA-approved indications for clinical use of the Androderm product.

33. Actavis and/or its predecessors-in-interest exhibited these indications on, among other places, the Prescribing Information ["PI"] as follows:

> **1 INDICATIONS AND USAGE**
>
> ANDRODERM is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
>
> - **Primary hypogonadism (congenital or acquired):** testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
> - **Hypogonadotropic hypogonadism (congenital or acquired):** idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

34. At all times material hereto, Actavis and/or its predecessors-in-interest knew and understood the medical and pathologic conditions and diagnoses, as set forth in the Androderm PI, which form and comprise the indications for clinical use of the Androderm product.

35. At all times material hereto, and since the launch of the Androderm products Actavis and/or its predecessors-in-interest knew and understood that the Androderm was not FDA-approved to treat:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

36. At all times material hereto, Actavis and/or its predecessors-in-interest knew and understood the meaning of the terms "off-label" use and "label expansion," and additionally knew and understood the FDA rules and regulations pertaining to these activities.

37. Actavis and/or its predecessors-in-interest knew and understood that when testosterone deficiency conditions occur prior to puberty, androgen replacement therapy is required during the adolescent years for development of androgen-dependent secondary sexual characteristics. Prolonged androgen treatment is then required to maintain sexual characteristics in these males following puberty.

38. Actavis and/or its predecessors-in-interest further knew and understood that androgen therapy may be indicated to stimulate puberty in males with delayed puberty, and that

these male patients generally manifest a form of familial-pattern pubertal delay that is not secondary to a pathological disorder. Rather, in these male patients, puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses of testosterone may be indicated in these patients if they do not respond to psychological support.

39. The FDA-approved indications for clinical use of the Androderm product do not and never have included the treatment of age-related declines in testosterone levels and age-related symptoms in men, including:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

40. Actavis and/or its predecessors-in-interest marketed Androderm in the United States through its own marketing, advertising, and branding teams; through marketing agreements; and through marketing firms, agencies, organizations, and/or other external pharmaceutical companies.

41. At all times material hereto, the marketing strategies of Actavis and/or its predecessors-in-interest included the use of sales or drug detailing representatives [“reps”] and

marketing and brand team personnel who performed on-line and in-person Androderm product detailing to physicians; and promotional and detailing to healthcare providers and physicians at medical organization and professional medical society meetings and conventions via display booths, sponsored meeting sessions, "satellite" sessions and meetings, and sponsored medical speakers.

42. Actavis and/or its predecessors-in-interest drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the Androderm product, product samples, as well as discount and/or rebate coupons to give to patients for the purchase of Androderm.

43. Actavis and/or its predecessors-in-interest drug "reps" detailed and marketed Androderm to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

44. Actavis and/or its predecessors-in-interest denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

45. The Androderm product was never approved by the FDA for "off-label" promotion for the treatment of "Low T" as an indication for clinical use.

46. Actavis and/or its predecessors-in-interest engaged in "label expansion" in both their promotion of Androderm use to physicians and in their marketing of Androderm to consumers and patients.

47. Actavis and/or its predecessors-in-interest marketed, promoted, and detailed Androderm for "off-label" use for the purpose of "label expansion" to populations of men who

were not appropriate candidates for testosterone treatment, and detailed and promoted the Androderm product to physicians, and advertised the Androderm product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the Androderm product.

48. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

49. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

50. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

51. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

52. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

53. At all times material hereto, Actavis and/or its predecessors-in-interest knew and understood that they had not provided the FDA with data supporting the clinical use of the Androderm product to treat age-related symptoms and:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

54. At all times material hereto, the marketing strategy of Actavis and/or its predecessors-in-interest for the Androderm products included the use of sales representative ["reps"] who performed detailing to physicians and mass promotional and detailing activities at professional medical organization and society meetings and conventions by way of display booths, sponsored speakers, sponsored presentations, and sponsored or recruited presenters.

55. The detailing "reps" of Actavis and/or its predecessors-in-interest provided physicians with:

a. information concerning the clinical indications for use of the Androderm product and medical literature;

b. product information and literature concerning testosterone, testosterone replacement therapy:

c. "Low T" and its treatment with Androderm;

d. "detailing pieces" and literature for distribution to patients;

e. invitations to Actavis and/or its predecessors-in-interest sponsored presentations and events; and

f. samples and/or discount and/or rebate coupons or vouchers and information about discount and/or rebate plans with respect to the purchase of Androderm for distribution to patients.

56. The sales "reps," promoters, and product detailers of Actavis and/or its predecessors-in-interest marketed and promoted the testosterone-containing Androderm product to physicians and healthcare providers as products approved and clinically indicated for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These were not FDA-approved clinical uses for these testosterone-containing products, and this was known to the sales "reps," promoters, and product detailers.

57. Actavis and/or its predecessors-in-interest marketed and promoted the testosterone-containing Androderm product directly to consumers as products approved and clinically indicated for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These were not FDA-approved clinical uses for these testosterone-containing products, and this was known to those marketing and promoting the Androderm product directly to consumers and patients.

58. Actavis and/or its predecessors-in-interest engaged in "off-label" promotion and misbranding of the testosterone-containing Androderm product during their marketing and detailing of this product to physicians and healthcare providers.

59. Actavis and/or its predecessors-in-interest engaged in "off-label" promotion and misbranding of the testosterone-containing Androderm product during their marketing and detailing of this product to consumers and patients.

60. Actavis and/or its predecessors-in-interest engaged in a direct-to-consumer marketing and promotional campaign through a variety of educational, advertising, and

informational multimedia platforms, including Internet-based dedicated "Low T" and "Androderm" websites and branded and unbranded television commercials.

61. Actavis and/or its predecessors-in-interest engaged in a direct-to-consumer marketing and promotional campaign through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T" and "Androderm" websites, which contained misbranding of the Androderm products.

62. Actavis and/or its predecessors-in-interest materially misrepresented and mischaracterized to consumers the definition and clinical etiologies and characteristics of hypogonadism, which is a specific medical disease with well-defined etiologies and pathologic conditions.

63. Actavis and/or its predecessors-in-interest in deceptive trade practices.

64. Actavis, by way of example, cites the 2006 "the HIM Study"[1] on the Androderm website as demonstrating that "[b]ased on the Hypogonadism in Males study, an estimated 13.8 million men aged 45 and older are testosterone deficient," and therefore have hypogonadism.

65. With respect to "the HIM Study:" "The goal of this study was to estimate the prevalence of hypogonadism in men aged at least 45 years presenting (for any reason)[2] to primary care practices in the United States. A second objective was to correlate the presence of hypogonadism with select comorbid conditions and symptoms."[3]

66. The study, as cited on the Androderm website, creates the false, deceptive, and misleading impression that 39% of men in the Unites States experience hypogonadism.

---

[1]Mulligan, T., Frick, M.F., Zuraw, Q.C. *et al.* (2006). Prevalence of hypogonadism in males aged at least 45 years: the HIM study. *Int J Clin Pract* 60:762-769.

[2]"Clinicians from a random sample of 2650 primary care practices throughout the United States were contacted and 130 practices agreed to participate. All men aged 45 years and older who were seen in a participating doctor's office between 8 AM and noon during a 2-week period, *regardless of the reason for their visit,* were invited to participate in the survey." *Id.* (emphasis added).

[3]*Id.*

67. Further, the website fails to acknowledge that this study was performed by, and on behalf of, the predecessor-in-interest to testosterone replacement product manufacturers Abbott and AbbVie, Solvay, and that several conflicts of interest existed with respect to this study:

CONFLICT OF INTEREST

Dr Thomas Mulligan has received funding from, and been a consultant for, Solvay Pharmaceuticals, Inc. He also does research for the Department of Veteran Affairs and Ascend Therapeutics and has been a consultant for GTx.

Myra Frick is an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

Dr Qing Zuraw is an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

Annette Stemhagen was formerly an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

68. The Androderm website does not identify these conflicts of interest.

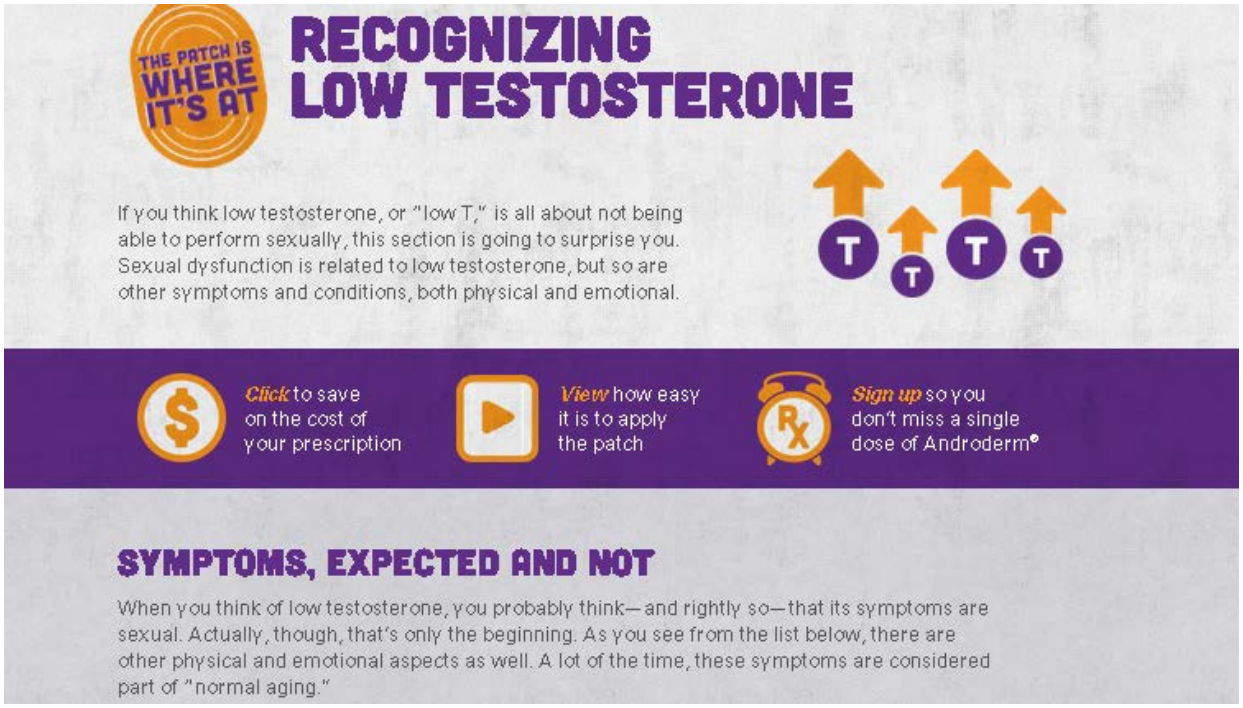
69. The Androderm website creates the false, misleading, and deceptive impression that "the HIM Study" was an independently performed assessment of hypogonadism, and significantly misstates the prevalence of hypogonadism.

70. "The HIM Study" is scientifically flawed in its design and conclusion to create the false and misleading impression amongst consumers and patients of a widespread epidemic of hypogonadism in men age 45 years or older.

71. Actavis and/or its predecessors-in-interest materially misrepresented and mischaracterized to consumers and patients the meaning of the term hypogonadism, and

provided misinformation concerning hypogonadism and "Low T" with the intent of confuse, deceive, and otherwise mislead consumers and patients to believe that "Low T," age-related declines in serum testosterone levels in men, and age-related symptoms in men are synonymous entities and pathologic conditions or diseases.

72. Actavis and/or its predecessors-in-interest materially misrepresented and mischaracterized to consumers and patients the meaning of the term hypogonadism with the intent of confuse, deceive, and otherwise mislead consumers and patients to believe that "Low T," age-related declines in serum testosterone levels in men, and age-related symptoms in men are synonymous entities and pathologic conditions or diseases suitable for treatment with the Androderm products.

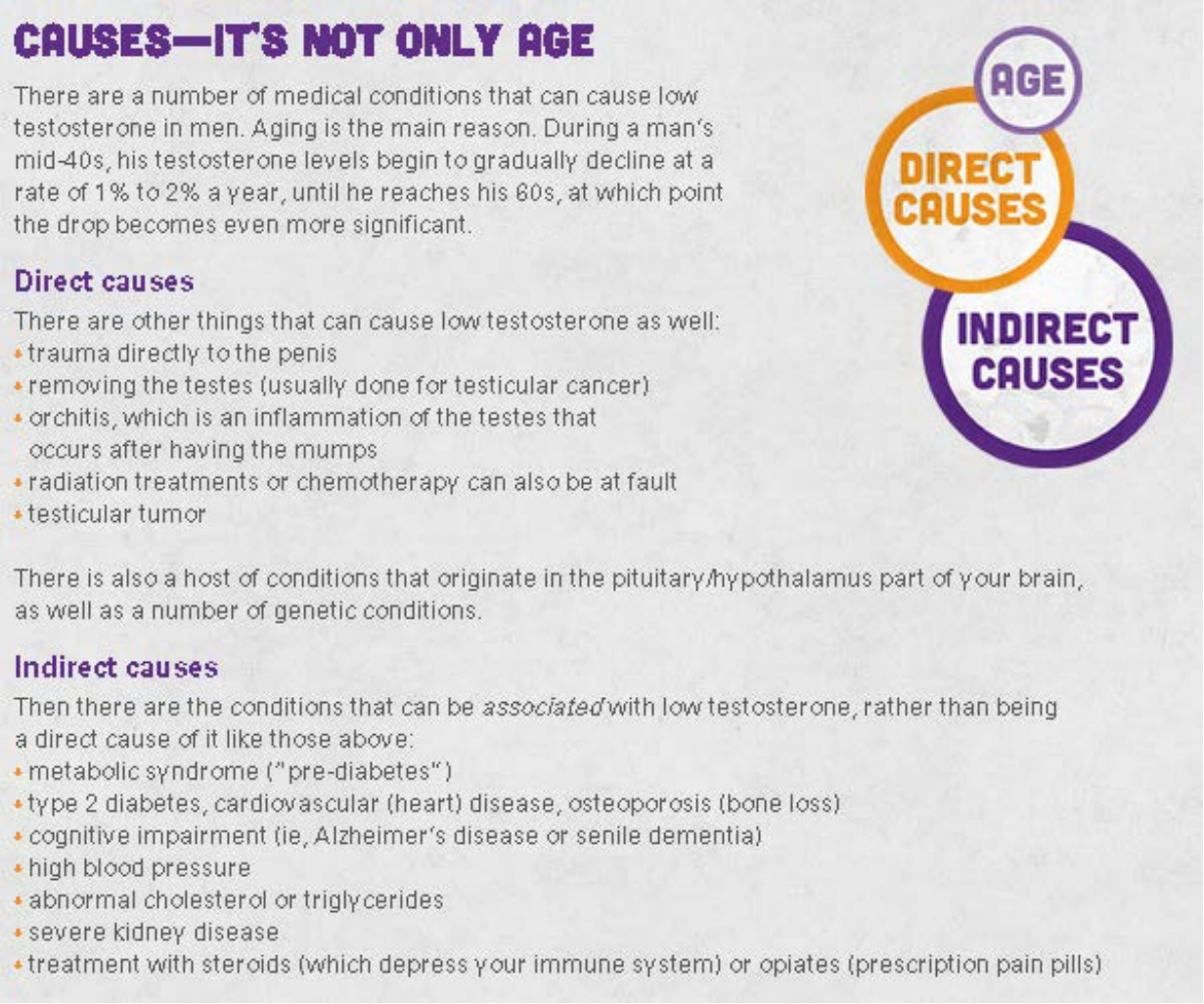


PHYSICAL	EMOTIONAL	SEXUAL
Hot flashes	Depressed mood	Diminished sexual desire
Decreased lean muscle mass	Emotional "ups and downs"	Inability to achieve or maintain an erection
Enlarged breasts	Mental "fuzziness"/ forgetfulness	Difficulty having an orgasm
Loss of body hair	Irritability	Decreased performance
Decreased strength	Decreased energy	Fewer nighttime and morning erections
Anemia (low red blood cell count)		
Frailty		
Tiring easily		
Increased body fat		
Sleep disturbances		

Reprinted from The American Journal of Medicine, Vol 124, Traish A et al, Testosterone Deficiency, 579-587, Copyright 2011, with permission from Elsevier.

73. Throughout their marketing and promotional campaigns to consumers, Actavis and/or its predecessors-in-interest misrepresented and mischaracterized the *normal* physiologic declines in testosterone levels in aging men and age-related symptoms in men as being synonymous with or an indication of the medical diagnosis of hypogonadism; and knowingly, falsely, deceptively, and inaccurately designated this contrived and medically unfounded form of "hypogonadism" as being "Low T."

74. Actavis represented to consumers that "Low T" was caused by "not only age" but also "Indirect causes:"



This representation is knowingly false, misleading, and deceptive.

75. Throughout their marketing and promotional campaigns to consumers and patients, Actavis and/or its predecessors-in-interest misrepresented and mischaracterized the *normal* physiologic declines in testosterone levels in aging men and age-related symptoms in men as being synonymous with or an indication of the medical diagnosis of hypogonadism; and knowingly, falsely, deceptively, and inaccurately marketed and promoted the Androgen product as an approved treatment for "Low T."

76. The FDA-approved the Androderm product for the treatment of primary and secondary hypogonadism.

77. Actavis and/or its predecessors-in-interest engaged in "off-label" marketing, promotional, and detailing campaigns which encouraged and drove "off-label" prescription and clinical use of the Androderm product with respect to the clinical indications for use of Androderm and the populations and subpopulations of patients suitable for treatment with Androderm product and for whom the product should be prescribed.

78. Actavis and/or its predecessors-in-interest knowingly, falsely, deceptively, and inaccurately educated and detailed physicians that Androderm was FDA-approved for the treatment of "Low T," and thereby engaged in "off-label" promotion and "label expansion," and enlisted and offered something of value to "thought leaders," "key opinion leaders," and sponsored speakers. These individuals assisted in the perpetuation of the "off-label" usage of the Androderm product through authored medical journal articles, speaking engagements, presentations at medical society meetings, including the American Urological Association, the Endocrine Society, and the American Andrology Society, and through their participation in the drafting of Clinical Practice Guidelines by these societies.

79. Actavis and/or its predecessors-in-interest made materially false and misleading statements about the nature of "Low T," and created the impression among consumers and patients that testosterone-replacement therapy in general, and the Androderm product line in particular, were approved treatments for age-related declines in testosterone levels and age-related symptoms in men.

80. "Low T" is not "a real medical condition."

81. Hypogonadism (primary and secondary) is a "real medical condition," not "Low T," and is the FDA-approved clinical indications for Androderm product administration.

82. "Low T" is not a disease, and does not have an assigned ICD code designator.

83. Actavis and/or its predecessors-in-interest were encouraging men to self-diagnose and self-assess themselves for the signs and symptoms of "Low T," a pharmaceutical industry created "disease."

84. In this manner, Actavis and/or its predecessors-in-interest provided consumers and patients with a means to self-assess and self-diagnose for the signs and symptoms of this pharmaceutical industry created disease, "Low T," prior to engaging or interfacing with a physician or other healthcare provider. Actavis and/or its predecessors-in-interest intended for patients to then request further evaluation for and treatment of "Low T" with Androderm.

85. Actavis and/or its predecessors-in-interest engaged in, promoted, and marketed "patient-directed medical care," in which patients were and continue to be encouraged to self-diagnose their "Low T" condition, and then seek out and direct their medical therapy from physicians.

86. Consumers and patients were encouraged to render their own self-diagnosis of "Low T," and to then seek medical treatment with the self-diagnosis and self-assessment of "Low T" already in hand.

87. The self-diagnosis of "Low T" by consumers and patients was therefore made according to diagnostic criteria posited by Actavis and/or its predecessors-in-interest.

88. Actavis and/or its predecessors-in-interest engaged in a mass program of consumer-based self-diagnostics and self-assessment which screened for signs and symptoms which Actavis and/or its predecessors-in-interest knew and understood were not approved indications for Androderm treatment; namely, age-related declines in testosterone levels and age-related symptoms in men.

89. Actavis and/or its predecessors-in-interest established programs for the Androderm product line to establish and maintain a "patient-pharmaceutical company" relationship with users and potential users of the Androderm products.

90. Actavis and/or its predecessors-in-interest provided dosing and refill reminders and information on Low T and information about Androderm directly to patients, without an intermediary physician, and established lines of communication directly with patients concerning Protected Health Information (PHI) independent of the involvement of healthcare providers.

91. Actavis and/or its predecessors-in-interest assumed and stepped into roles coterminous with but separate and apart from healthcare providers, including:

a. offering consumers and patients extensive medical information concerning a "disease," including its signs, symptoms, etiology, and associated co-morbidities;

b. advising patients concerning the treatment and/or treatment options for that "disease;"

c. providing assistance in the diagnosis of the "disease" by taking a detailed history of patient signs and symptoms, and recommending or directing laboratory testing for the "disease;"

d. providing prescription refill reminders;

e. providing information about specific drug therapy for the "disease, including adverse effects of the therapy;" and

f. soliciting Protected Health Information (PHI) and data concerning the health status of patients, including prior or current medical conditions.

92. Actavis and/or its predecessors-in-interest specifically detailed and promoted the use of the Androderm products to prescribing physicians for clinical use in patients with "Low T," which Actavis and/or its predecessors-in-interest knowingly, deceptively, and falsely claimed was included in and fell under the clinical definition of hypogonadism.

93. Actavis and/or its predecessors-in-interest assumed and undertook a duty of care when they chose to educate and inform consumers about "Low T;" when they chose to provide consumers with the means for self-diagnostic assessment and screening for "Low T;" and when they offered differential diagnoses for signs and symptoms which Actavis and/or its predecessors-in-interest claimed were consistent with or indicative of "Low T."

94. The duty of care of Actavis and/or its predecessors-in-interest included the obligation to provide truthful, accurate, and incomplete information about "Low T," including information that "Low T" is not an indication for clinical use of testosterone-containing preparations in general, and the Androderm product in particular.

95. Actavis and/or its predecessors-in-interest expressly and impliedly warranted to consumers that the Androderm product was an FDA-approved treatment for "Low T" and age-related symptoms; that Androderm had a favorable clinical safety and effectiveness profile for the treatment of "Low T" and age-related symptoms; and that Androderm was an appropriate treatment for this particular purpose. This was a "basis of the bargain" upon which consumers, including the Plaintiff-husband, justifiably relied in their choice to accept treatment with, purchase, and administer the Androderm product.

96. Actavis and/or its predecessors-in-interest expressly and impliedly warranted to consumers that the Androderm product line was an FDA-approved treatment for "Low T" and age-related symptoms; that Androderm had a favorable clinical safety and effectiveness profile for the treatment of "Low T" and age-related symptoms; and that Androderm was an appropriate treatment for this particular purpose. This was a "basis of the bargain" upon which consumers, including the Plaintiff-husband, relied in their choice to accept treatment with, purchase, and administer an Androderm product.

97. The duty of care to consumers and patients of Actavis and/or its predecessors-in-interest included providing accurate, true, complete, full, and correct information concerning hypogonadism and its diagnostic criteria; the FDA-approved indications for the clinic use of the Androderm product line; the clinical safety and effectiveness profiles of Androderm; and the full

and complete panoply of warnings about the adverse effects of Androderm, including the risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

98. Actavis and/or its predecessors-in-interest knowingly, falsely, deceptively, and inaccurately designated the age-related physiologic decrease in men's testosterone levels and the age-related symptoms which men experience with senescence as a form of acquired hypogonadism with the intent to deceive or otherwise encourage physicians to prescribe Androderm for "off-label" indications for clinical use; to engage in "label expansion" of the Androderm product in order to increase revenues and profits through market expansion; and to drive increasing consumer demand for Androderm prescriptions.

99. Actavis and/or its predecessors-in-interest knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of Androderm to physicians, to include statements concerning the effectiveness of treatment of the age-related symptoms. There was no evidence to support this clinical use of the Androderm products, and no approval by the FDA to warrant promotion of these indications of clinical use for the Androderm.

100. Actavis and/or its predecessors-in-interest knowingly, falsely, deceptively, and inaccurately designated the physiologic declines in men's testosterone levels and age-related symptoms men experience as a form of "acquired hypogonadism," with the intent to confuse, mislead, and deceive consumers and patients, and to foster the belief among consumers and patients, including the Plaintiff-husband, that they harbored a "disease" that was appropriately and effectively treated with an Androderm product.

101. Consumers, including the Plaintiff-husband, required truthful, accurate, full, complete, and correct information concerning the FDA-approved indications for clinical use of the Androderm product and Androderm therapy, and the clinical safety and effectiveness profiles of the Androderm product.

102. Consumers and patients, including the Plaintiff-husband, were never informed by Actavis and/or its predecessors-in-interest that Androderm was being promoted, marketed, detailed, and endorsed for "off-label" clinical uses.

103. Neither Actavis, nor its predecessors-in-interest informed consumers about the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

104. Actavis and/or its predecessors-in-interest knowingly encouraged and drove the demand for laboratory testing for testosterone levels premonitory to the clinical diagnosis and treatment of "Low T," with actual knowledge that "Low T" and age-related symptoms in men are not indications for treatment with an Androderm product.

105. Actavis and/or its predecessors-in-interest failed to disclose to physicians that the FDA had not approved the use of Androderm product for the treatment of age-related declines in testosterone levels in men or age-related symptoms in men, and that the FDA knew of no data supporting these indications for use.

106. At all times material hereto, Actavis and/or its predecessors-in-interest made false and misleading statements and claims to physicians regarding the clinical safety and effectiveness profiles of Androderm and its spectrum of FDA-approved indications for use.

107. At all times material hereto, Actavis and/or its predecessors-in-interest promoted and marketed Androderm products to physicians and healthcare providers, and failed to warn of the known risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular injuries causally related to the use of Androderm.

108. Actavis and/or its predecessors-in-interest knew and understood that there were no prospective, randomized, long-term-use clinical trials which demonstrated either the clinical safety or effectiveness of testosterone therapy for age-related declines in testosterone levels or age-related symptoms in men, and that the FDA had not approved these as indications for Androderm use.

109. Neither Actavis, nor its predecessors-in-interest ever informed the FDA that it was engaging in "label expansion" through its physician marketing, and promotional and

detailing activities to include the use of the Androderm product "off-label" to treat "Low T" or age-related declines in testosterone levels or to age-related symptoms in men.

110. This "label expansion" for Androderm by Actavis and/or its predecessors-in-interest exceeded the FDA-approved clinical uses to treat of primary and secondary hypogonadism.

111. At all times material hereto, Actavis and/or its predecessors-in-interest owed a duty to prescribing physicians to inform these physicians of the approved uses for the Androderm product, and to warn prescribing physicians that the FDA had not approved Androderm product for the treatment of age-related declines in testosterone levels and age-related symptoms in men.

112. At all times material hereto, Actavis and/or its predecessors-in-interest had a duty to warn physicians that Androderm was being promoted for "off-label" indications for clinical use, and that there was no appropriately developed, controlled, suitably powered, and independent data to support this use.

113. At all times material hereto, Actavis and/or its predecessors-in-interest knowingly deceived physicians, including the Plaintiff-husband's prescribing physician, concerning the FDA-approved uses for the Androderm product and the clinical indications for Androderm therapy.

114. At all times material hereto, Actavis and/or its predecessors-in-interest knowingly deceived physicians, including the Plaintiff-husband's prescribing physician, concerning the clinical safety and effectiveness profiles of the Androderm product.

115. At all times material hereto, Actavis and/or its predecessors-in-interest intentionally sought to simultaneously deceive, mislead and confuse consumers, on the one hand,

concerning the approved clinical indications for use of the Androderm products, the products' safety and effectiveness profiles, and the definitions of hypogonadism; and on the other hand, the physicians prescribing Androderm, to whom the product was knowingly, willfully, and deceptively being detailed and promoted for "off-label" use. These activities were undertaken to promote and increase "off-label" prescription and clinical use of the Androderm products.

116. At all times material hereto Actavis and/or its predecessors-in-interest disseminated and provided information during the promotion and detailing of the Androderm products to physicians and healthcare providers, including the Plaintiff-husband's prescribing physician, which failed to disclose the correct and accurate FDA-approved indications for use of the Androderm product line.

117. The information provided to healthcare providers was false, misleading, and deceptive, and failed to warn that the product was being promoted for "off-label" clinical indications for use and that safety and effectiveness profiles were lack in the patient populations and subpopulations for which Actavis and/or its predecessors-in-interest were advocating product use.

118. At all times material hereto, Actavis and/or its predecessors-in-interest had, undertook, and assumed a continuing duty to correct the known misinformation which had been disseminated to physicians, healthcare providers, patients, and consumers concerning the FDA-approved indications for clinical use of the Androderm product; the lack of clinical safety and effectiveness profiles for Androderm; and the relationship of Androderm to heart attacks, strokes, deep vein thrombosis, pulmonary emboli, sudden cardiac death, and risk factors for these disease states. Actavis and/or its predecessors-in-interest failed in these duties.

119. At all times material hereto, Actavis and/or its predecessors-in-interest misbranded the Androderm product on an on-going and continuous basis, and failed to warn that the Androderm product line was not approved for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

120. At all times material hereto, Actavis and/or its predecessors-in-interest sought to conflate the diagnosis of hypogonadism with the diagnosis of "Low T."

121. Actavis and/or its predecessors-in-interest sales "reps" and promotional and marketing teams detailed the Androderm product line to physicians, including the Plaintiff-husband's physician, as an appropriate FDA-approved treatment for "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

122. The treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms with Androderm products created a manifest and unreasonable public health hazard, including a hazard to the Plaintiff-husband, because patients with "Low T" should not have been exposed to treatment with Androderm product.

123. Actavis and/or its predecessors-in-interest knew and understood that consumers and patients would rely upon the educational and medical information that they provided through its multi-platform marketing, promotional, and awareness campaigns concerning the Androderm product line and its indications for clinical use; and further knew that consumers and patients would make treatment choices and decisions about their use of the Androderm product in justifiable reliance upon this information.

124. As marketed, detailed, and promoted to physicians, Actavis and/or its predecessors-in-interest failed to warn physicians that Androderm caused or increased the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

125. At all times material hereto, Actavis and/or its predecessors-in-interest had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Androderm product to cause, or increase the harm of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

126. At all times material hereto, and presently, neither Actavis, nor its predecessors-in-interest have warned physicians, consumers, or patients of the risks of serious adverse life-

and limb-threatening cardiovascular and cerebrovascular events caused by or increased in the risk of harm by the Androderm product.

127. Androderm should not have been designed for the treatment of age-related declines in testosterone levels and age-related symptoms in men; or the treatment of "Low T;" and should not have been promoted for, prescribed for, or used for these clinical purposes.

128. Safer pharmaceutical and non-pharmaceutical alternatives to Androderm treatment of "Low T" or age-related declines in testosterone levels in men or age-related symptoms in men existed which were FDA-approved and/or of known safety and effectiveness for the treatment of these conditions.

129. Androderm was negligently designed for the treatment of "Low T."

130. The Plaintiff-husband relied to his detriment upon the fraudulent representations, misrepresentations, misinformation, and express and implied warranties made by or provided by Actavis and/or its predecessors-in-interest with respect to the Androderm product.

131. The Plaintiff-husband would not have sought, accepted, or continued treatment for "Low T," or administered Androderm, or continued with or otherwise undergone testosterone replacement therapy, had he been provided with adequate, true, accurate, and correct information by Actavis and/or its predecessors-in-interest about the risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events causally associated with the of increased in their risk of harm by the use of Androderm, and the fact that "Low T" was not an FDA-approved indication for use for the Androderm product line.

132. The Plaintiff-husband would not have sought or continued treatment for "Low T," or administered Androderm, had he been provided with adequate, true, accurate, and correct

information by Actavis and/or its predecessors-in-interest that there was no proven clinical profile of safety or effectiveness for the use of Androderm to treat "Low T."

133. Actavis and/or its predecessors-in-interest failed to warn physicians of the hazards and dangers of the Androderm product to cause, or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

134. Actavis and/or its predecessors-in-interest failed to warn consumers and patients of the hazards and dangers of the Androderm products to cause or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

135. The Androderm website advises consumers:

ALLEGATIONS AS TO THE SUBJECT
TESTOSTERONE REPLACEMENT THERAPY PRODUCTS

136. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

137. The foregoing general allegations as to testosterone replacement therapy set forth in the subsequent paragraphs are applicable to all claims set forth herein.

138. The FDA scheduled a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee for September 17, 2014 to "discuss the appropriate indicated population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes associated with this use."[4]

139. On January 31, 2014, the FDA announced an investigation into the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products.[5]

140. The FDA's announcement was based on two published studies which highlighted enhanced cardiovascular risks among men prescribed testosterone therapy:[6]

a. R. Vigen, C.I. O'Donnell, A.E. Barón, *et al.* (November 6, 2013). Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels. *JAMA* 310(7): 1829-1836 ["Vigen Study"], and

b. W.D. Finkle, S. Greenland, G.K. Ridgeway *et al*. Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men. *PlosOne* 9(1):1-7 ["Finkle Study"].

141. In 2010, S. Basaria, A.D. Coviello, T.G. Travison et al. published an article in the *New England Journal of Medicine* entitled "Adverse Events Associated with Testosterone Administration."[7] ["Basaria Paper"].

142. The clinical study reported in the Basaria Paper was prematurely discontinued because the Data and Safety Monitoring Board (DSMB) overseeing the safety of the subjects

[4]FDA (July 17, 2014). *September 17, 2014 Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting Announcement* at http://www.fda.gov/advisorycommittees/calendar/ucm404905.htm.
[5]*See* FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.
[6]*Id.*
[7]*N Engl J Med 363*(2):109-122 (July 8, 2010).

enrolled in this study observed a significant number of adverse cardiovascular events in the testosterone-treated group.

143. The Basaria Paper concluded, among other things: "In this population of older men with limitations in mobility and a high prevalence of chronic disease, the application of a testosterone gel was associated with an increased risk of cardiovascular adverse events. The small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy. (ClinicalTrials.gov number, NCT00240981.)."[8]

144. The FDA has noted:

> Testosterone is a hormone essential to the development of male growth and masculine characteristics. Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition.[9] Examples of these conditions include failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy. Other examples include problems with brain structures, called the hypothalamus and pituitary that control the production of testosterone by the testicles.
>
> None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition. FDA-approved testosterone formulations include the topical gel, transdermal patch, buccal system (applied to upper gum or inner cheek), and injection.[10]

145. The testosterone-containing product manufacturer herein advantaged the intentional ambiguity in the testosterone product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians. This ambiguity was additionally advantaged through the recruitment of "thought leaders," "key opinion leaders," and sponsored and funded researchers and research in testosterone replacement therapy, who promoted "off-

[8] *Id.*
[9] The medical conditions are specifically delineated in the product PPI.
[10] FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.

label" testosterone product use and "label expansion" through the medical literature and presentations.

146. The testosterone-containing product herein is not indicated for the treatment of the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

147. The testosterone-containing product manufacturer herein marketed and promoted these products for treatment of both the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

148. Constellations of age-related physiologic findings, including the *normal* age-related declines in testosterone levels and non-specific age-related symptoms, have been conscripted into a pharmaceutical industry created pseudo-medical condition known as "Low-T."

149. "Low T" is not a disease, and does not have an International Classification of Disease (ICD) code.

150. The testosterone-containing product manufacturer herein performed aggressive and highly effective marketing and promotional campaigns directed at both the consuming public and healthcare providers, and have driven a dramatic, unwarranted, and dangerous increase in testosterone product usage over the past decade. This has created a substantial public health problem in the United States and elsewhere.

151. A substantial number of prescription sales are for clinical uses of testosterone that are not approved by the FDA,[11] and are the result of aggressive and pervasive "off-label" promotion by testosterone-containing product manufacturers, including the manufacturer herein.

152. The scientifically established propensity of testosterone products to cause hypercoagulability and hyperviscosity syndromes was known prior to the launch of the

[11]Between 2001 and 2011, testosterone replacement therapy has increased three-fold. *See* Baillargeon, J., Urban, R.J., and Ottenbacher, K.J. (2013). Trends in Androgen Prescribing in the United States. *JAMA* 173(15):1465-1466.

testosterone-containing products described herein, and should have been warned about to physicians and the public *ab initio*.[12]

153. The scientifically established propensity of testosterone products to cause hypercoagulability and hyperviscosity syndromes was known prior to the launch of the testosterone-containing products described herein, and information concerning these propensities should have been provided in the safety information which the manufacturer herein undertook, as a duty, to provide to consumers and patients.

154. TRT Sponsors AbbVie, Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, LillyEndo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal have stated to the FDA in their *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* in advance of the September 17, 2014 Advisory Committee[13] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

155. At all times material hereto, despite being "committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions," these testosterone-containing product manufacturers, sellers, distributors, promoters, and marketers made no labelling changes concerning the risks associated with their testosterone containing product use, include the risk of:

a. heart attacks and consequent myocardial damage;

[12]*See, e.g.,* Schrör K., Morinelli T.A.,Masuda A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl. 1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

[13]Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

156. It is well-known that the *normal* aging process is accompanied by a physiologic decline in testosterone levels.

157. On July 8, 2010, Dr. W.J. Bremner published an editorial in the *New England Journal of Medicine* entitled "Testosterone Deficiency and Replacement in Older Men",[14] observing:

> The diagnosis of testosterone deficiency in older men is complicated by the fact that many older men (more than 20% in some studies) have testosterone levels that are lower than the normal range in younger men. In addition, the clinical presentation of male hypogonadism is nonspecific and overlaps with that of other illnesses and with the aging process itself. Therefore, it is frequently unclear in caring for individual older patients whether the diagnosis of hypogonadism is appropriate and whether testosterone administration might be helpful or might instead cause adverse effects.

158. Two observational studies have prompted the FDA to investigate the risk of adverse cardiovascular events associated with testosterone replacement therapy.

159. The Vigen Study identified a 30% increase in the risk of heart attack, stroke, or death in the study group prescribed testosterone therapy when compared to a group that did not receive testosterone replacement therapy.

160. The results of this study led Dr. Anne R. Cappola to observe:

[14] *N Engl J Med* 363(2):189-191.

> In light of the high volume of prescriptions and aggressive marketing by testosterone manufacturers, prescribers and patients should be wary. There is mounting evidence of a signal of cardiovascular risk, to which the study by Vigen et al. contributes. This signal warrants both cautious testosterone prescribing and additional investigation.[15]

161. The Finkle Study reported a two-fold increase in the risk of heart attack in men 65 years of age and older in the first 90 days following their first testosterone prescription. In men less than 65 years of age who harbored a pre-existing history of heart disease, the Finkle Study reported a two- to three-fold increased risk of heart attack in the first 90 days following a first prescription.

162. Testosterone replacement therapy results in the potential increase in hematocrit[16] and serum estradiol level.[17]

163. Testosterone administration is associated with suppression of serum hepcidin.

164. Increases in hematocrit in older men during testosterone therapy are related to the greater effect of suppression of hepcidin. "Testosterone administration is associated with suppression of serum hepcidin. Greater increases in hematocrit in older men during testosterone therapy are related to greater suppression of hepcidin." [18]

[15]Cappola, A.R. (2013). Editorial: Testosterone Therapy and Risk of Cardiovascular Disease in Men. *JAMA* 310(17):1805-1806.
[16]Fernández-Balsells, M.M, Murad, M.H., Lane, M. *et al.* (2010). Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. *J Clin Endocrin Metab* 95(6):2560–2575; *see also* Bachman, E., Travison, T., Basaria, S. *et al.* (2013). Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. *J Gerontol A Biol Sci Med* at http://jmh.sagepub.com/content/early/2014/02/19/1557988314522642.full.pdf+html.
[17]Finkelstein, J.S., Lee, H., Burnett-Bowie, S.M. *et al.* (2013). Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men, *N Eng J Med* 369:1011-22.
[18]Eric Bachman, E., Feng, R., Travison, T., *et al.* (2010). Testosterone Suppresses Hepcidin in Men: A Potential Mechanism for Testosterone-Induced Erythrocytosis. *J Clin Endocrinol Metab* 95: 4743–4747.

165. Additionally, testosterone effects the expression of platelet thromboxane A2 receptors. The latter significantly increases platelet aggregation,[19] leading to a state of hypercoagulability.

166. Increases in hematocrit and estradiol are associated with hyperviscosity and hypercoagulability syndromes, and well-known risks of thrombosis leading to serious adverse cardiovascular and cerebrovascular ischemic events.[20]

167. In 1968, W. Fried and C.W. Gurney published an article in the *Annals of the New York Academy of Sciences* entitled "The Erythropoietic-Stimulating Effects of Androgens"[21] in which these authors described the capacity of androgenic steroids to induce erythrocytosis. "Drastic elevations of hematocrit may be detrimental to patients with underlying coronary, cerebral or peripheral vascular disease by possibly causing an increase in blood viscosity and increased risk of thrombosis."[22]

168. An elevated hematocrit is an independent risk factor for adverse cardiovascular events.[23]

---

[19]Ajayi, A.A., Mathur, R., Halushka, P.V. (1995). Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. *Circulation* 91: 2742-2747.

[20]Wannamethee, G., Perry, I.J., Shaper, A.G. (1994). Haematocrit, hypertension and risk of stroke. *J Intern Med* 235(2):163-8; *see also* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245; Braekkan, S.K., Mathiesen, E.B., Njølstad, I. *et al.* (2010). Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. *Haematologica* 95(2):270-5; Cinar,Y., Demir, G., Paç, M. *et al.* (1999). Effect of hematocrit on blood pressure via hyperviscosity. *Am J Hypertens* 12(7):739-43; Glueck, C.J., Friedman, J., Hafeez, A., *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Blood Coagul Fibrinolysis* 25 (ePub ahead of print); Glueck, C.J., Richardson-Royer, C., Schultz, R. *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Clin Appl Thromb Hemost* 20(1):22-30.

[21]*Ann NY Acad Sci* 149:356–365.

[22]Stergiopoulos, K., Brennan, J.J., Mathews *et al.* (2008). Anabolic Steroids, Acute Myocardial Infarction and Polycythemia: A Case Report and Review of the Literature. *Vascular Health and Risk Management* 4(6) 1475–1480.

[23]*See* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012), *supra* at f.n.19; *see also* Kunnas, T., Solakivi,T., Huuskonen, K. *et al.* (2009). Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. *Prev Med* 49 (1):45–47 (In this study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.).

169. The *Framingham Heart Study* demonstrated a strong, graded relationship between hematocrit level and the risk of developing congestive heart failure.[24] In 3,523 *Framingham Heart Study* participants aged 50 to 65 years who were free of a history of heart failure at baseline, and who were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had nearly double the risk of new-onset heart failure during follow-up.[25]

170. An additional study using *Framingham Heart Study* data demonstrated that in lifetime nonsmokers, those in the highest hematocrit category (>45.0 for women, >49.0 for men) had greater than twice the risk for heart failure.[26]

171. The relationship between hematocrit level and cardiovascular risk is mediated by erythropoietin (EPO). Overexpression of the EPO gene in in-bred mice results in extremely high hematocrit levels and leads to increased cardiac weight, left ventricular dilation, and decreased survival compared to wild-type mice.[27]

172. An elevated hematocrit among users of exogenously administered testosterone results from an elevation in EPO levels. This effect is most pronounced at 1 and 3 months following initial treatment.[28]

173. EPO can also activate platelets, causing an enhanced risk of thrombosis as shown in patients receiving exogenous EPO who have underlying cardiovascular diseases.[29]

---

[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] Wagner, K.F., Katschinski, D.M., Hasegawa, J. *et al.* (2001). Chronic inborn erythrocytosis leads to cardiac dysfunction and premature death in mice overexpressing erythropoietin. *Blood* 97:536–542.
[28] *See* Bachman, E., Travison, T., Basaria, S. *et al.* (2013), *supra* at f.n. 16.
[29] Smith, K.J., Bleyer, A.J., Little, W.C. *et al.* (2003). The Cardiovascular Effects of Erythropoietin. *Cardiovasc Res* 59:538-548.

174. Elevated EPO and its effect on hematocrit has been positively correlated with an increased risk of developing heart failure, even after adjusting for conventional heart failure risk factors.[30]

175. Elevated estradiol levels are also an independent risk factor for adverse cardiovascular events.[31,32,33]

176. Thromboxane A2 is a potent vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease.

177. Thromboxane A2 is produced by activated platelets and has prothrombotic properties: It stimulates activation of new platelets as well as increases platelet aggregation.

178. A 1995 study demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response. This contributes to the thrombogenicity of androgenic steroids such as testosterone.[34]

179. Thromboxane A2 has been implicated in a range of cardiovascular diseases secondary to its acute and chronic effects on platelet aggregation, vasoconstriction, and vascular endothelial proliferation. In vitro, animal and human studies have established the central role of thromboxane A2 in cardiovascular disease.[35]

---

[30]Coglianese, E .E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245.

[31]Khader, Y.S., Rice, J., John, L. *et al.* (2003). Oral contraceptives use and the risk of myocardial infarction: a meta-analysis. *Contraception 68*(1):11-17; *see also* Baillargeon, J.P., McClish, D.K., Essah, P.A. *et al.* (2005). Association between the current use of low-dose oral contraceptives and cardiovascular arterial disease: a meta-analysis. *J Clin Endocrinol Metab* 90(7):3863-3870 .

[32]Mohamad, M.J., Mohammad, M.A., Karayyem, M. *et al.* (2007). Serum Levels of Sex Hormones in Men with Acute Myocardial Infarction. *Neuro Endocrinol Lett* 28(2):182-6.

[33]Jankowska, E.A., Rozentryt, P., Ponikowska, B. *et al.* (2009). Circulating Estradiol and Mortality in Men with Systolic Chronic Heart Failure. *JAMA* 301(18):1892-1901.

[34]*See, e.g.,* Schrör, K., Morinelli, T.A., and Masuda, A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl. 1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

[35]*See* Katugampola, S.D. and Davenport, A.P. (2001). Thromboxane receptor density is increased in human cardiovascular disease with evidence for inhibition at therapeutic concentrations by the AT1 receptor antagonist

180. "Low-T" is a distinct and separate entity from the conditions for which testosterone replacement therapy has been FDA-approved; namely, for the conditions of primary hypogonadism and secondary hypogonadism.

181. "Hypogonadism in a male refers to a decrease in one or both of the two major functions of the testes: sperm production or testosterone production. These abnormalities can result from disease of the testes (primary hypogonadism) or disease of the pituitary or hypothalamus (secondary hypogonadism)."[36]

182. Outside the United States, foreign regulatory bodies are taking definitive action with respect to concerns related to the increased risk of adverse cardiovascular outcomes associated with testosterone replacement therapy.

183. On July 15, 2014, Health Canada initiated a safety review to evaluate the currently available information regarding the cardiovascular risks associated with the use of testosterone replacement products.[37] Following a detailed safety review, Health Canada made the following conclusion with respect to the association between adverse cardiovascular outcomes and the use of testosterone replacement therapy:

Losartan. *Br J Pharmacol* 134:1385–1392; *see also* Cheng, Y., Austin, S.C., Rocca, B. *et al.* (2002). Role of prostacyclin in the cardiovascular response to thromboxane A2. *Science* 296:539–541 (Demonstrating the reciprocal relationship between thromboxane and prostacyclin *in vivo*); Kobayashi, T., Tahara, Y., Matsumoto, M. *et al.* (2004). Roles of thromboxane A2 and prostacyclin in the development of atherosclerosis in ApoE-deficient mice. *J Clin Invest* 114:784–794; Xiao, C.Y., Hara, A., Yuhki, K., *et al.* (2001). Roles of prostaglandin I2 and thromboxane A2 in cardiac ischemia–reperfusion injury: a study using mice lacking their respective receptors. *Circulation* 104:2210–2215; Cayatte, A.J., Du, Y., Oliver-Krasinski, J. *et al.* (2000). The thromboxane receptor antagonist S18886 but not aspirin inhibits atherogenesis in ApoE-deficient mice: evidence that eicosanoids other than thromboxane contribute to atherosclerosis. *Arterioscler Thromb Vasc Biol* 20:1724–1728; Hirata, T., Kakizuka, A., Ushikubi, F. *et al.*, Arg60 to Leu mutation of the human thromboxane A2 receptor in a dominantly inherited bleeding disorder. *J Clin Invest* 94:1662–1667 (Reporting a naturally occurring TP mutation associated with a mild bleeding disorder).

[36]Snyder, P.J. (2014). Clinical features and diagnosis of male hypogonadism. *Up-To-Date* at http://www.uptodate.com/contents/clinical-features-and-diagnosis-of-male-hypogonadism?source=search_result&search=hypogonadism&selectedTitle=1%7E150.

[37]*See* Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/review-examen/testosterone-eng.php.

> The current available evidence suggests the possibility that cardiovascular problems, other than those already identified, may occur with the use of testosterone replacement products. The use of these products in Canada (and internationally) has been increasing and findings from a Canadian study raise additional concerns that these products may not always be used within the approved patient population.[38]

184. As a result of the above-identified conclusions, Health Canada implemented the following actions:

a. Health Canada is working with manufacturers to update the Canadian product label for testosterone replacement products regarding possible cardiovascular risks including heart attack, stroke, blood clots in the lungs or legs, and irregular heart rate;

b. Health Canada has communicated to Canadians on the possible cardiovascular risk associated with testosterone replacement products; and

c. Health Canada is collaborating with foreign regulators including the U.S. Food and Drug Administration and the European Medicines Agency regarding this safety concern.[39]

185. The substantial "off-label" promotion and use of testosterone-containing products has been well-known to the product manufacturer herein.

186. As stated by the Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy in *Testosterone and Aging: Clinical Research Directions*, Institute of Medicine of the National Academies (2004):

> The benefits of testosterone therapy for markedly hypogonadal males have been well established. Hypogonadism is defined as "inadequate gonadal function, as manifested by deficiencies in gametogenesis and/or the secretion of gonadal hormones" (Stedman's Medical Dictionary, 2000). Male hypogonadism is categorized as primary or secondary (also termed central) based on the location of the disorder. In primary hypogonadism, the testes do not function properly for reasons including surgery, radiation, genetic and developmental disorders, infection, or liver and kidney disease. The most common genetic disorder

[38] *Id.*
[39] *Id.*

> resulting in primary hypogonadism in men is Klinefelter's syndrome, in which there is an extra sex chromosome, XXY. Primary hypogonadism is characterized by low levels of testosterone with elevated levels of the gonadotropins, FSH and LH.
>
> Secondary (or hypogonadotropic) hypogonadism is the result of disorders in the pituitary gland or hypothalamus. Causes of secondary hypogonadism include pituitary tumors, surgery, radiation, infections, inflammation, trauma, bleeding, genetic problems, nutritional deficiency, and iron excess (hemochromatosis) (Medline Plus, 2002). In secondary hypogonadism testosterone levels are low, while the levels of FSH and LH remain in the low to low-normal range.

187. In 2004, The Institute of Medicine of the National Academies of Science Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy stated:

> The committee's task was to identify the research needed to determine if testosterone is an efficacious treatment option for older men. This approach does not directly address the research needed to determine whether current off-label use, particularly by middle-aged men, is either efficacious or safe. The committee has concerns about the growing use of testosterone by men who do not meet the clinical definition of hypogonadism in the absence of controlled trials needed to determine efficacy and safety.[40]

188. In 2006, Daniel A. Shames, M.D. from the FDA stated in the *New England Journal of Medicine*:

> More than 50 years ago, physicians began treating the "male climacteric" with testosterone. Since then, no standardized definition of this condition has been developed, no metric defining a therapeutic effect has been created, no randomized controlled studies have been conducted to support the widespread use of testosterone in men for this condition, and the adverse-event profile of the drug in this population has not been studied adequately. The Food and Drug Administration (FDA) has not approved testosterone for this condition.[41]

[40]The Institute of Medicine of the National Academies of Science Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy (2004). *Testosterone and Aging Clinical Research Directions*. (Catharyn T. Liverman and Dan G. Blazer, eds.).
[41]*N Engl J Med* 350:2004-2006 (May 6, 2004).

189. The Endocrine Society, which promulgates guidelines for the use of testosterone-containing medications, including Androderm, among others, observed and stated in 2014 that "many patients in the U.S. are being prescribed testosterone for the treatment of age-related symptoms or age-related decline in testosterone levels, for which testosterone therapy has not been approved by the Food and Drug Administration."[42]

190. Dr. Peter J. Snyder from the University of Pennsylvania, who maintains a relationship with the pharmaceutical industry and testosterone replacement therapy market sector by way research sponsorship by Abbott, AbbVie, and or predecessors-in-interest, has stated:

> **Inappropriate use of testosterone in healthy middle-aged men** —There has been a dramatic increase in inappropriate use of testosterone therapy in healthy middle-aged and older men. This is likely due, at least in part, to direct-to-consumer advertising encouraging use of testosterone products for nonspecific symptoms, such as decreased energy and sexual interest.[43]

191. Increasing testosterone levels via the administration of exogenous testosterone in in men experiencing age-related declines in testosterone levels and age-related symptoms of "Low T" are not FDA-approved indications for the clinical use of current prescription testosterone-containing products, and represents "off-label" promotion for the clinical uses of the these pharmaceutical products.

192. Safer alternative formulations and strategies existed and continue to exist to treat these conditions.

193. Such uses of the testosterone-containing product described herein created, and continue to create, unreasonable and foreseeable health hazards, including the induction of

---

[42]*The Risk of Cardiovascular Events in Men Receiving Testosterone Therapy: An Endocrine Society Statement* (February 7, 2014) at https://www.endocrine.org/~/media/endosociety/Files/Advocacy%20and%20Outreach/Position%20Statements/Other%20Statements/The%20Risk%20of%20Cardiovascular%20Events%20in%20Men%20Receiving%20Testosterone%20Therapy.pdf.

[43]Snyder, P.J. and Matsumoto, M.A. (updated May 16, 2014). Testosterone treatment of male hypogonadism. *Up-To-Date*.

hypercoagulable states, increased levels of estradiol generated by the metabolism of exogenously administered testosterone, a reduction in high-density lipoprotein ["HDL"], and an increase in low density lipoprotein ["LDL"], without any proven benefit from the use of "off-label" use of these products to treat "Low T".

194. These cardiovascular and cerebrovascular disease factors create a physiologic milieu in men which causes or increases the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

195. Exposure of men to these health hazards and risks was and remains unwarranted and reflects and continues to reflect consumer exploitation via reckless, wanton, and fraudulent promotion and marketing of non-approved indications for the testosterone product described herein.

196. Induction of a hypercoagulable state, increased levels of estradiol, a reduction in HDL, and an increase in LDL are risk factors for serious adverse cardiovascular events and cerebrovascular accidents, and cause or increase the risk of harm of these events.

197. Longitudinal and cross-sectional studies of healthy men have demonstrated that a decrease in testosterone levels is a *normal* component of the aging process.[44]

198. This medical information was known in advance of and available at the time of the launch and/or during the product lifecycle of the testosterone-containing product herein.

199. Physiologic declines in testosterone levels are a component of the *normal* male aging process and affects approximately 20% or more of the United States male population over 50 years of age. Declines in *normal* testosterone levels continue thereafter with aging.

200. The standard treatment for age-related declines in testosterone levels and age-related symptoms in men is not testosterone therapy. These conditions are not subsumed under nor do they meet the definition of hypogonadism as set forth in the FDA-approved clinical indications for Androderm use.

201. Increasing testosterone levels via the administration of exogenous testosterone in men experiencing age-related declines in testosterone levels and age-related symptoms of "low energy levels, loss of sex drive, decreased muscle mass and mild depression" are not FDA-approved clinical indications for use of Androderm, and reflects and represents the "off-label" promotion and use of Androderm, and "label expansion" for Androderm use.

202. Such uses of the testosterone product herein create unreasonable and foreseeable health hazards, including the induction of hypercoagulable and hyperviscosity conditions and states, increased levels of estradiol generated by the metabolism of exogenously administered testosterone, a reduction in high-density lipoprotein, and an increase in low density lipoprotein, without any proven benefit from product use.

[44]Bagatell, C.J. and Bremner.W.J. (1998). II. Changes in Reproductive Hormones During the Aging Process. *JCE&M* 83(10):3436.

203. These factors create a physiologic milieu in men which causes or increases the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

204. Exposure of men to these health hazards and risks was unwarranted, and reflected consumer and patient exploitation through the reckless, wanton, deceptive, and fraudulent promotion and marketing of non-approved indications for testosterone-containing product prescription and use.

205. Induction of a hypercoagulable state, increased levels of estradiol, a reduction in HDL, and an increase in LDL are risk factors for serious adverse cardiovascular events and cerebrovascular accidents, and cause, or increase the risk of harm of these events, including the Plaintiff-husband's injuries and damages.

206. Longitudinal and cross-sectional studies of healthy men have demonstrated that a decrease in testosterone levels is a normal component of the aging process.[45]

207. The increased incidence of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events was foreseeable to the testosterone-containing product

[45]Bagatell, C.J. and Bremner, W.J. (1998). II. Changes in Reproductive Hormones During the Aging Process. *JCE&M* 83(10):3436.

manufacturers at or before the time of the product launch of the testosterone-containing products described herein.

208. The manufacturer of testosterone-containing product herein engaged a cadre of "thought leaders," "key opinion leaders," and speakers, including individuals with leadership positions in influential scientific organizations and societies (e.g., the Endocrine Society and the American Urological Association) to offer opinions which supported and advocated "off-label" clinical indications for testosterone therapy, including the products described herein.

209. In the 2010 *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline*, the authoring Task Force from the Endocrine Society lists the following financial disclosures:

Financial Disclosure of Task Force

Shalender Bhasin, M.D. (Chair)—Consultation or Advisement: GlaxoSmithKline (GSK), Merck; Grant or Other Research Support: Abbott Laboratories, Ligand, Merck; Financial or Business/Organizational Interests: American Board of Internal Medicine. **Glenn R. Cunningham, M.D.**—Consultation or Advisement: Clarus, Columbia Lab, GSK, Endo Pharmaceuticals, Abbott Laboratories; Grant or Other Research Support: Abbott Laboratories; Columbia Lab, GSK; Speakers List: Columbia Lab, Endo Pharmaceuticals, Abbott Laboratories; Financial or Business/Organizational Interests: UpToDate; Significant Financial Interest or Leadership Position: none declared. **Frances J. Hayes, M.B., FRCPI**—Consultation or Advisement: Auxilium Pharmaceuticals, GSK, New England Research Institute; Speakers Bureau for Abbott Laboratories; Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared. **Alvin M. Matsumoto, M.D.**—Consultation or Advisement: Abbott Laboratories, Merck, Endo Pharmaceuticals, Tokai; Grant or Other Research Support: GSK, Abbott Laboratories; Financial or Business/Organizational Interests: UpToDate, U.S. Anti-Doping Agency/PCC; Significant Financial Interest or Leadership Position: none declared. **Peter J. Snyder, M.D.**—Consultation or Advisement: none declared; Grant or Other Research Support: Abbott Laboratories; Financial or Business/Organizational Interests: Abbott Laboratories, UpToDate; Significant Financial Interest or Leadership Position: UpToDate. **Ronald S. Swerdloff, M.D.**—Consultation or Advisement: Clarus, Abbott Laboratories, Endo Pharmaceuticals; Grant or Other Research Support: Actelion Pharma, ARYx Therapeutics, Inc., Auxilium, Bayer Corp., Besins/Ascend, Bristol-Myers Squibb, Clarus, Columbia, Corcept, GSK, Eli Lilly &Co., MacroChem Corp., Organon, Schering AG, Abbott Laboratories; Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared. ***Victor M. Montori, M.D.**—Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared.

210. With respect to the 2010 *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline*:

> Aside from medical societies' support of educational ventures and research, they advocate for their members and for patients, and provide guidance about professional behavior. Many, if not all of these activities, can be corrupted by financial conflicts. The existence of examples in which society/industry connections may have led to adverse consequences does not necessarily prove that the problems uncovered are widespread, but given the secrecy, it is simply not possible to know the extent of the problem. What follows are several specific examples that illustrate the various ways in which medical societies' activities can be compromised.
>
> The first example is a clinical recommendation. A practice guideline published by the Endocrine Society on androgen deficiency and its treatment in elderly men recommended that testosterone should be measured when hormone deficiency is suspected (they suggested all men over age 50), and that a course of testosterone treatment might be warranted even if testosterone levels were not low when a man's symptoms (lack of energy, for example) suggested hormone deficiency (Kassirer 2004).These recommendations were made not only despite the unreliability of tests for the diagnosis of testosterone deficiency, but in the face of the risk that testosterone treatment can accelerate the growth of prostate cancer, a condition that is common in the very age group proposed for treatment. Notably, a report on the same subject at nearly the same time from the National Institutes of Health (NIH) came to different conclusions (Thorner et al. 2001). It cited the difficulties in measuring testosterone and the lack of a well proven way to make the diagnosis, and urged great caution in treating men suspected of having the condition until more research was available. Why the discrepancy? In a 2002 issue of the New Yorker magazine, physician Jerome Groopman found a possible explanation. The experts at the NIH had no financial ties either with companies that offered testosterone testing or testosterone treatments. By contrast, many members of the Endocrine Society panel had financial ties with Solvay, the company that markets AndroGel, a widely used testosterone preparation. Solvay had also supported the panel's work financially and had nominated some Endocrine Society members who later joined the panel. The Endocrine Society's recommendations were tainted by the financial conflicts.[46]

[46]Kassirer, J.P. (winter 2007). Professional Societies and Industry Support: what is the quid pro quo*?* *Perspectives in Biology and Medicine*. 50(1):7-17.

211. As observed by Drs. L.M. Schwartz, and S. Woloshin in the article "Low T as a Template: How to Sell as Disease" in *JAMA* 173(15):1460-1462 (August 12/26, 2013) (emphasis added) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: ***a mass, uncontrolled experiment*** that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. ***Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm***.

212. Performing "a mass, uncontrolled experiment" on patients by way of testosterone-containing product sales, distribution, "off-label" promotion, and marketing without the safeguards of informed consent, independent oversight of patient well-being, and Institutional Review Board approval is shocking, outrageous, reckless, wanton, and undertaken in reckless disregard to the safety and well-being of patients and the public-at-large.

213. The testosterone-containing product manufacturer herein engaged in false and deceptive screening of consumers and patients through the use of self-diagnostic questionnaires and "Low T" self-assessment quizzes.

214. Dr. John Morley ["Dr. Morley"], Director of Endocrinology and Geriatrics at the St. Louis University School of Medicine, developed the ADAM[47] Questionnaire at the request of the Dutch pharmaceutical company, Organon BioSciences ["Organon"], in exchange for a $40,000 grant to his university.

[47] "**A**ndrogen **D**eficiency in **A**dult **M**ales."

215. Organon instructed Dr. Morley: "Don't make it too long and make it somewhat sexy."

216. Thereafter, Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on pieces of toilet paper, and subsequently gave the questions to his secretary to type the next day.

217. Dr. Morley has stated that he has "no trouble calling it a crappy questionnaire," noting that it is "not ideal."[48]

218. At all times material hereto, both the Endocrine Society and the European Association of Urology had recommended against using "Low T"-type screening quizzes and self-assessment questionnaires because these methods were known to be unreliable and unvalidated.

219. The ADAM Questionnaire was specifically designed to drive "off-label" prescription and use of testosterone-containing products, and to promote "label expansion."

220. The testosterone-containing product manufacturer herein knowingly misrepresented to consumers and patients that testosterone replacement therapy was approved by the FDA for the treatment of age-related declines in testosterone levels or age-related symptoms as "part of a broad effort to influence how doctors and the public think about what constitutes disease and when drugs are 'needed,'" and to "blur the line between public health or professional education and marketing."[49]

[48]Singer, N. (Nov. 13, 2013). Selling that New-Man Feeling, *NY Times*.

[49]*"Low T": How to Sell Disease* (June 4, 2013) at http://tdi.dartmouth.edu/press/updates/low-t-how-to sell-disease.

221. On June 19, 2014, the FDA mandated that a general warning be added to the testosterone-containing products concerning venous blood clots:[50]

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

222. On October 5, 2014, the FDA Center for Drug Evaluation and Research published the approved Summary Minutes of the Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee held on September 17, 2014[51] [the October 5, 2014 minutes are referred to as "Summary Minutes of the Joint Meeting" and the two participating committees as the "Joint Committees"].

223. In the October 5, 2014 Summary Minutes of the Joint Meeting, the Joint Committees reported the following:

> The joint committees agreed that the use of testosterone replacement products in men with inherited or acquired loss of testosterone production in conjunction with a recognized disease condition ("classical hypogonadism") was supported by data. There was general consensus that the current paradigm for drug development is not capable of generating

[50]http://www.fda.gov/Drugs/DrugSafety/ucm401746.htm.

[51]http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCom.

> data in support of testosterone replacement therapy for "age-related hypogonadism". Committee members agreed that the current information supports an indication only for classical hypogonadism and not for age-related hypogonadism. There was consensus that the labeling for testosterone needs to be revised accordingly to reflect the appropriate indicated population. Some committee members expressed a concern that age-related hypogonadism had not yet been established as a disease condition. Two members opined that testosterone therapy may be justified in selected older men with significant hypogonadal signs/symptoms and documented 'very low' serum testosterone concentrations (e.g., less than 100 ng/dL). However, even these two committee members recognized the need for additional research to assess the effectiveness of testosterone therapy for this patient population. The joint committees agreed that the use of testosterone therapy for symptomatic men without documented low testosterone levels was not appropriate.

224. The Joint Committees further acknowledged in the Summary Minutes of the Joint Meeting that:

> [T]he available studies informing the cardiovascular safety signal with testosterone therapy are limited in scope, quality, design, and size. Nonetheless, there was agreement amongst committee members that a weak signal of cardiovascular risk had emerged from results of recent large epidemiologic studies. Given this signal coupled with biologic plausibility for cardiovascular-related adverse events with testosterone use, committee members believed that the need for additional studies was critical and that some commented that clinical trials for safety would be necessary…Overall the committee agreed that the potential signal for cardiovascular risk should be added to the labeling. Most committee members recommended cautionary wording that would reflect the known information regarding potential risk, while a few others suggested a boxed warning.

225. The Summary Minutes of the Joint Meeting further reported that:

> There was virtual unanimous agreement that FDA should revise the current indication for the class of testosterone replacement therapy. Committee members stated that the indication should limit testosterone replacement therapy to men with classical hypogonadism. The committees commented that the label should include statements to address the potential cardiovascular risks of testosterone therapy, the importance of proper testing of serum testosterone concentrations to confirm the diagnosis, and that efficacy and safety in age-related hypogonadism have not been established.

226. The members of the Joint Committees "reiterated the need to revise the testosterone labeling to clarify that the efficacy and safety for testosterone therapy in age-related hypogonadism have not been established."

227. The labelling for the subject testosterone product was false, misleading, deceptive, and intentionally crafted and structured to render the false and misleading impression that "Low T" was a form of "classical hypogonadism."

228. "Low T" is not a form of "classical hypogonadism" as advertised, promoted, and marketed to consumers and patients, including the Plaintiff-husband.

229. "Low T" is not a form of "classical hypogonadism" as advertised, promoted, and marketed to physicians and other healthcare providers, including the Plaintiff-husband's prescribing physician.

230. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients treated with testosterone-containing products for the diagnosis of "Low T," including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment." Such conduct is outrageous and shocks the conscience.

231. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" by fraudulently characterizing "Low T" as a form of "classical hypogonadism" warranting testosterone-replacement therapy.

232. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" by engaging in "label expansion" and "off-label" administration by representing to physicians, including the Plaintiff-husband's prescribing

physician, that "Low T" or age-related decreases in testosterone levels and age related symptoms were a form of "classical hypogonadism" warranting testosterone-replacement therapy.

233. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized the consuming public, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" in "label expansion" and "off-label" testosterone product administration through false, misleading, and deceptive trade practices in which "Low T" was characterized as a form of "classical hypogonadism" warranting testosterone-replacement therapy.

ALLEGATIONS SPECIFIC TO THE PLAINTIFFS' INJURIES AND DAMAGES

234. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

235. Plaintiffs file this lawsuit within the applicable statute of limitations.

236. The Plaintiff-husband sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him by direct-to-consumer educational and informational "Low T" awareness campaigns initiated and propagated by the aforementioned manufacturers of testosterone-containing product.

237. The Plaintiff-husband's prescribing physician would not have prescribed testosterone replacement therapy to his patient had he been advised of and warned of the dangers of cardiovascular events and cerebrovascular accident set forth herein caused by or increased with respect to the risk of harm by these testosterone-containing products.

238. The Plaintiff-husband would not have used the aforementioned testosterone-containing products had he been advised and warned of the of the dangers of serious adverse life-

and limb-threatening cardiovascular and cerebrovascular injuries caused by or increased with respect to the risk of harm by these products.

239. The Plaintiff-husband justifiably relied upon the claims and representations of the aforementioned manufacturers that testosterone-replacement therapy of "Low T" had been clinically demonstrated to be safe and effective when used to raise testosterone levels for this clinical indication, and that these products were approved for use for that particular purpose.

240. The Plaintiff-husband reasonably relied upon the implied and expressed claims and representations of the testosterone-containing manufacturers set forth herein that their products had been approved by the FDA for the treatment of "Low T," and were safe and effective.

241. The Plaintiff-husband is 42 years old, and had a prior medical history of diabetes, smoking, and a hip replacement.

242. In or around December 2012 until in or around March 2014, the Plaintiff-husband was treated with Androderm.

243. Plaintiff-husband was prescribed Androderm by a physician assistant.

244. Under California practice requirements, physician assistants cannot practice independently and must be supervised by a licensed physician.

245. The supervising physician is responsible for all medical services provided by a physician assistant under his/her supervision and for following each patient's progress.

246. On March 4, 2014, Plaintiff-husband underwent cardiac catheterization with angioplasty, stenting, and thrombus aspiration for an acute anteroseptal myocardial infarction.

247. The Plaintiff-husband's myocardial infarction was directly and proximately caused by, or had the risk of harm increased by the testosterone-containing medication Androderm.

248. Because of his use of Androderm, and the resultant myocardial infarction caused, or increased in harm, by this product, the Plaintiff-husband has suffered, and continues to suffer:

a. pain and suffering

b. loss of life's pleasures

c. physical debility

d. mental anguish

e. fear and fright

f. embarrassment and humiliation

g. economic loss

h. requirement for medical monitoring

i. past, present, and future medical expenses

249. The Plaintiff-wife herein brings a derivative claim for the loss of marital consortium.

THEORIES OF LIABILITY AND DEMANDS FOR RELIEF

COUNT I-NEGLIGENCE

250. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

251. Actavis and/or its predecessors-in-interest placed Androderm into the stream of interstate commerce at the time of product launch in or about 1995.

252. At all times material hereto, Actavis and/or its predecessors-in-interest had a duty to exercise reasonable and prudent care in Androderm's design, promotion, advertising, marketing, labelling, warnings, instructions for use, post-marketing safety monitoring, surveillance and pharmacovigilance, and safety-signal detection.

253. The Plaintiff-husband's prescribing physician was within the market to which Actavis and/or its predecessors-in-interest directed their product marketing, physician-detailing, advertising, and promotional strategies, initiatives, activities, and efforts, and accordingly was a reasonably foreseeable user.

254. The Plaintiff-husband was within the market to Actavis and/or its predecessors-in-interest directed their product marketing, physician-detailing, advertising, and promotional sales strategies, initiatives, activities, and efforts and accordingly was a reasonably foreseeable user.

255. At all times material hereto, Actavis and/or its predecessors-in-interest had a duty to ensure that the Androderm product did not cause end-users to suffer serious life- and limb-threatening cardiovascular and cerebrovascular injuries through the failure of Actavis and/or its predecessors-in-interest, and those promoting Androderm on behalf of Actavis and/or its predecessors-in-interest, to provide adequate warnings, information concerning the FDA-approved indications for use, and instructions for product use to prescribing physicians.

256. At all times material hereto Actavis and/or its predecessors-in-interest had a duty not to misbrand the Androderm product, or to promote the product for "off-label" indications for use.

257. At all times material hereto, Actavis and/or its predecessors-in-interest entered into a concerted drug detailing plan for the purpose of educating and raising the awareness of physicians about "Low T" and the clinical uses of Androderm for the treatment of age-related

declines in testosterone levels and age-related symptoms in order to inappropriately increase physician prescribing habits for the Androderm product.

258. The goal of Actavis and/or its predecessors-in-interest was to promote "off-label" prescribing and "label expansion" for the Androderm product.

259. At all times material hereto, Actavis and/or its predecessors-in-interest knew, or should have known, that the FDA-approved indications for use of the Androderm product did not include "Low T" or age-related declines in testosterone levels or age-related symptoms men, and that detailing and promoting the product for these indications for use was inappropriate, unreasonably dangerous, and encouraged "off-label" prescribing and use.

260. Actavis and/or its predecessors-in-interest had a duty to advise and warn physicians with respect to the FDA-approved uses for Androderm, and to refrain from detailing and promoting the Androderm product for "off-label" use.

261. The Androderm products were imminently and unreasonably dangerous when used as intended for treating "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

262. Androderm products were not reasonably fit, suitable or safe for the ordinary and foreseeable purpose for which it was sold by Actavis and/or its predecessors-in-interest, which was the treatment of "Low T.

263. Androderm was negligently designed for the intended and promoted use of Actavis and/or its predecessors-in-interest of treating "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

264. Actavis and/or its predecessors-in-interest knew, or should have known, that the Androderm product was imminently and unreasonably dangerous when put to its detailed and promoted indications for use.

265. Androderm was not FDA-approved to treat "Low T," and had no clinical profiles of either safety or effectiveness for this use or purpose.

266. Actavis and/or its predecessors-in-interest failed to warn physicians of the lack of clinical safety and effectiveness profiles for the indications for which it was promoting the product for "off-label," non-FDA-approved indications for clinical use.

267. Actavis and/or its predecessors-in-interest knew, or should have known, that the Androderm product, which contained testosterone, would cause or increase the risk of harm of hypercoagulable and hyperviscosity states, increased estradiol levels via the known metabolic pathways for exogenously administered testosterone, decreased HDL, and increased LDL.

268. Actavis and/or its predecessors-in-interest, or should have known, that Androderm causes or increases the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries and their consequences, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

269. This information and knowledge was available to and known by Actavis and/or its predecessors-in-interest at the time of the Androderm product launch in or about 1995, and should have been, but was not, disclosed to physicians by way of appropriate and adequate warnings.

270. Actavis and/or its predecessors-in-interest knew, or should have known, during the period in which it was promoting the Androderm product, that Androderm, as an exogenously administered testosterone-containing preparation, caused or increased the risk of harm of factors responsible for adverse serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

271. This information and knowledge was available to and known by Actavis and/or its predecessors-in-interest at the time of the Androderm product launch in or about 1995, and throughout this product's lifecycle.

272. Actavis and/or its predecessors-in-interest failed to warn physicians, including the Plaintiff-husband's prescribing physician, of the risk of serious adverse life- and limb-threatening cardiovascular and cerebrovascular injuries caused by or increased in the risk of harm by the use of Androderm.

273. Actavis and/or its predecessors-in-interest failed to warn physicians, including the Plaintiff-husband's prescribing physician, that the Androderm product was not approved by the FDA for the treatment of age-related declines in testosterone levels or age-related symptoms in men, and that the drug was being detailed and promoted to physicians for extensive "off-label" prescribing and "label expansion."

274. Actavis and/or its predecessors-in-interest failed to warn prescribing physicians, including the Plaintiff-husband's prescribing physician, by way of physician detailing, general

marketing and promotion, labelling, the Product Package Insert, Prescribing Information, the Physician's Desk Reference, and Internet-based physician promotional campaigns, that Androderm had no proven clinical profiles of safety or effectiveness when used to treat age-related decreases in testosterone levels and age-related symptoms in men.

275. The warnings to physicians provided by Actavis and/or its predecessors-in-interest, including the Plaintiff-husband's prescribing physician, were inadequate, and caused or increased the risk of harm of the Plaintiff-husbands injuries and damages.

276. As designed, Actavis and/or its predecessors-in-interest should not have placed Androderm into the stream of interstate commerce for the treatment of age-related declines in testosterone levels or age-related symptoms in men.

277. Treatment of these conditions had approved and safer alternative treatment modalities, including medications for the treatment of erectile dysfunction, antidepressant medications, weight loss medications, exercise programs, and counseling for depressive disorders.

278. The Plaintiff-husband's physician would not have prescribed testosterone therapy to his patient had he been adequately and appropriately warned about the accompanying risks of Androderm administration, including serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

279. The Plaintiff-husband would have discussed the risks and benefits of Androderm use with his physician had the Plaintiff-husband been advised and informed that Androderm was being marketed and promoted for "off-label" indications for use, and of the foreseeable health hazards of serious life- and limb-threatening cardiovascular and cerebrovascular injuries caused or increased in the risk of harm by Androderm.

280. The Plaintiff-husband would not have administered the Androderm product had he been advised by his prescribing physician that "Low T" or age-related declines in testosterone levels and age-related symptoms were "off label" indications for product use which do not carry the approval of the FDA, and for which there was no demonstrated proof of benefit or safety.

281. The Plaintiff-husband's prescribing physician would have discussed the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries with his patient, and would have informed his patient of those risks, if they had been made known to him, as they should have been, by Actavis and/or its predecessors-in-interest.

282. Actavis and/or its predecessors-in-interest failed to warn prescribing physicians in general, and the Plaintiff-husband's prescribing physician in particular, that Actavis and/or its predecessors-in-interest was detailing and promoting Androderm for "off-label" use in a patient population where such treatment was inappropriate, unapproved, and with no proven benefit.

283. The breach of the duty to warn by Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's grave injuries, and caused the loss of consortium experienced by the Plaintiff-wife.

284. The negligent design of the Androderm product by Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's grave injuries and damages, and caused the loss of consortium experienced by the Plaintiff-wife.

285. Accordingly, Actavis is liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT II—NEGLIGENCE

286. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

287. "One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) the harm is suffered because of the other's reliance upon the undertaking."[52]

288. Actavis and/or its predecessors-in-interest gratuitously undertook comprehensive patient awareness, educational, and interactive consumer and patient directed campaigns via:

a. direct-to-consumer renditions of medical and diagnostic information;

b. product testimonials and endorsements;

c. proffered differential diagnoses for patient signs and symptoms;

d. comprehensive information concerning testosterone therapy and its clinical uses and safety;

e. solicitation of Protected Health Information (PHI);

f. providing various iterations, characterizations, and definitions of the pathologic "disease" which it denominated as "Low T;"

g. recommendations for laboratory testing;

h. assistance with medical insurance and third-party payer coverage for Androderm therapy;

i. prescription refill reminders; and

j. offers of ongoing contact regarding medical information and treatment plans.

[52] *Restatement (Second) of Torts § 323* (1965).

289. Actavis and/or its predecessors-in-interest set out to recast well-defined disease states and pathologic conditions of the testes and the hypothalamic-pituitary-gonadal axis, which comprise primary and secondary hypogonadism, to include the diagnosis of "Low T."

290. "Low T" is an age-related decrease in testosterone levels and age-related symptoms in men.

291. Actavis and/or its predecessors-in- recast "Low T" as a form of hypogonadism to create a market niche for the "off-label" use of the Androderm product.

292. Actavis and/or its predecessors-in-interest knew, or should have known, that age-related declines in testosterone levels and age-related symptoms in men were not included in the FDA-approved spectrum of indications for use of Androderm, and that the Androderm product was being marketed and promoted for "off-label" use directly to consumers and patients, including to the Plaintiff-husband.

293. Actavis and/or its predecessors-in-interest sought to misrepresent and conflate the age-related decline in testosterone levels and age-related symptoms in men with a true disease condition, hypogonadism, and should have known, that such a misrepresentation would drive men to seek medical diagnostic evaluation, testing, and treatment for "Low T."

294. Actavis and/or its predecessors-in-interest assumed and undertook duties separate and apart from, but coterminous with, roles traditionally reserved for and undertaken by healthcare providers, including:

a. offering consumers and patients extensive medical information concerning a "disease," including signs, symptoms, etiology, and associated co-morbidities;

b. advising patients concerning the treatment and/or treatment options for that "disease;"

c. providing assistance in the diagnosis of the "disease" by taking a detailed history of patient signs and symptoms, and recommending or directing laboratory testing for the "disease;"

d. providing information about specific drug therapy for the "disease;"

e. providing patients with physician referrals for evaluation and treatment;

f. soliciting Protected Health Information (PHI) and data concerning the health status of patients, including prior or current signs and symptoms; and

g. maintaining an ongoing and relationship with the patient to provide further medical information.

295. Actavis and/or its predecessors-in-interest owed a duty of care to the Plaintiff-husband to provide accurate, true, and correct information to avoid physical harm.

296. Actavis and/or its predecessors-in-interest, knew, or should have known, that there were no long-term, placebo-controlled, double-blind, sufficiently powered, and independent clinical studies or trials which demonstrated any benefit to testosterone therapy for age-related declines in testosterone levels and age-related symptoms in men, and should have provided, but did not provide, such information in its promotions to consumers and patients.

297. Actavis and/or its predecessors-in-interest undertook to educate and inform consumers and patients about the medical condition of "Low T" and its treatment, and owed a duty to inform consumers and patients, including the Plaintiff-husband, that testosterone therapy

for age-related declines in testosterone levels or age-related symptoms in men were not FDA-approved uses or clinical indications for product use.

298. Actavis and/or its predecessors-in-interest knew that the FDA had not approved Androderm for the treatment of "Low T," and that "Low T" was not a disease or a form of hypogonadism.

299. Actavis and/or its predecessors-in-interest owed a duty to inform consumers and patients of the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries caused or increased in the risk of harm by Androderm.

300. Actavis and/or its predecessors-in-interest failed to inform consumers, including the Plaintiff-husband, that the Androderm product was not indicated for the treatment of "Low T" or the relief of symptoms claimed to be secondary to "Low T" on the Androderm website.

301. Actavis and/or its predecessors-in-interest breached their duty of care to provide true, accurate, and correct medical information to the Plaintiff-husband, which it gratuitously undertook to perform, and thereby caused or increased the risk of harm of injury and damages to the Plaintiff-husband.

302. The Plaintiff-husband would not have sought treatment for "Low T" or used Androderm had he been appropriately and adequately informed by Actavis and/or its predecessors-in-interest, through their comprehensive medical information and awareness campaigns with respect to the Androderm product, of the true, correct, and accurate FDA-approved status of Androderm, including the approved indications for clinical use of Androderm.

303. The Plaintiff-husband would not have administered or continued to administer Androderm to himself had he been informed by Actavis and/or its predecessors-in-interest that the FDA-approved indications for use for Androderm did not include the treatment of age-related declines in testosterone or age-related symptoms in men, and that he was being prescribed a product that Actavis and/or its predecessors-in-interest were promoting for "off-label" use to physicians.

304. The Plaintiff-husband would not have administered Androderm had he been informed by Actavis and/or its predecessors-in-interest that he was a participant in "a mass, uncontrolled experiment" through his use of the Androderm product.

305. The Plaintiff-husband reasonably and justifiably relied upon the representations and medical information provided by Actavis and/or its predecessors-in-interest concerning their Androderm product to his detriment, and suffered bodily injury and damages caused by or increased in the risk of harm by his use of Androderm.

306. The negligence of Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages, and caused the loss of consortium experienced by the Plaintiff-wife.

307. Accordingly, Actavis is liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT III-RECKLESSNESS AND WANTONESS

308. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

309. The reckless and wanton conduct of Actavis and/or its predecessors-in-interest, and their reckless disregard for the safety and well-being of the Plaintiff-husband, gives rise to a claim for punitive damages.

310. Actavis and/or its predecessors-in-interest consciously, willfully, and deliberately engaged in conduct which was carried out with a reckless, wanton, and conscious disregard for the rights and safety of others, including the Plaintiffs and the public-at-large.

311. Actavis and/or its predecessors-in-interest used the Plaintiff-husband as a participant in "a mass, uncontrolled experiment" through his use of the Androderm product.

312. Human experimentation without appropriate safeguards and consent is outrageous, wanton, reckless, and shocks the conscience.

313. Actavis and/or its predecessors-in-interest crafted a two-pronged promotional scheme which included willfully and wantonly providing consumers and patients with misinformation about the indications for use of the Androderm product in order to drive consumer-originated demand for diagnostic evaluation of and treatment for "Low T;" coupled with an aggressive campaign of deceptive and misleading physician education, promotion, and detailing with misinformation about the approved clinical uses of Androderm.

314. This two-pronged scheme was formulated and executed to encourage, promote, and increase "off-label" treatment of men with Androderm, and to initiate "label expansion" of the Androderm clinical indications for use.

315. Actavis and/or its predecessors-in-interest was complicit with co-promoters of the Androderm product in an insidious and well-crafted two-pronged promotional scheme, which included:

a. the willful and wanton promotion, co-promotion, and marketing strategy to consumers and patients which consisted of intentionally misinformation about the indications for clinical use of the Androderm product in order to drive consumer-originated demand for diagnostic evaluation of and treatment for "Low T;"

b. coupled with an aggressive and deceptive campaign of physician education, promotion, and detailing with misinformation regarding the approved clinical uses, safety, and effectiveness of Androderm.

316. Actavis and/or its predecessors-in-interest intentionally and deliberately undertook these activities to encourage, promote, and increase "off-label" treatment of men with Androderm.

317. This combined consumer marketing and physician detailing strategy and plan was undertaken with actual knowledge that Androderm's label was being inappropriately expanded beyond the confines of its FDA-approved indications for clinical use, and in the absence of scientific and clinical evidence with respect to the safety and effectiveness profiles of Androderm in the setting of expanded and "off-label" product use to treat "Low T."

318. Actavis and/or its predecessors-in-interest willfully, and in reckless and wanton disregard for public safety, including the safety and well-being of the Plaintiff-husband, expanded the label of Androderm therapy beyond primary and secondary hypogonadism, to include age-related declines in testosterone levels and age-related symptoms in men. This constituted "a mass, uncontrolled experiment" that was shocking and unconscionable.

319. At all times material hereto, Actavis and/or its predecessors-in-interest knew that the FDA had not approved Androderm for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

320. At all times material hereto, and since the time of that Androderm was approved by the FDA, Actavis and/or its predecessors-in-interest knew that the FDA had not approved Androderm as therapy:

a. to improve mood;

b. to increase sexual interest;

c. to restore erectile function;

d. to increase muscle mass; or

e. to increase strength of bones.

321. At all times material hereto, Actavis and/or its predecessors-in-interest knew and understood that the FDA was unaware of any data to support these indications for clinical use of Androderm.

322. Actavis and/or its predecessors-in-interest withheld and suppressed material information concerning the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries causally associated with testosterone use.

323. Actavis and/or its predecessors-in-interest willfully and wantonly set out to expose men to the Androderm product, by way of "a mass, uncontrolled experiment," to treat conditions for which Androderm was neither approved nor indicated for clinical use.

324. Actavis and/or its predecessors-in-interest willfully and wantonly set out to expose men to the Androderm product, by way of "a mass, uncontrolled experiment," to treat conditions for which Androderm's clinical safety data and effectiveness profiles were lacking.

325. Actavis and/or its predecessors-in-interest had actual knowledge of Androderm's capacity to cause serious life- and limb-threatening cardiovascular and cerebrovascular injuries, including the Plaintiff-husband's injuries and damages, through biologic and physiologic mechanisms which were known at the time of the Androderm product launch in or about 1995.

326. These mechanisms include the induction of hypercoagulable states, hyperviscosity and rheological abnormalities of blood flow, increases in estradiol levels generated by the metabolism of exogenously administered testosterone, a decrease in HDL, and an increase in LDL, all of which are well-known and well-established risk factors for serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

327. At all times material hereto, despite possessing actual knowledge of the grave risks of injuries and death to consumers and patients which result from predicate factors for serious life- and limb-threatening cardiovascular and cerebrovascular injuries, Actavis and/or its predecessors-in-interest took no action to provide adequate or amended warnings to prescribing physicians or to consumers and patients.

328. Despite actual knowledge of known serious adverse potentially life- and limb-threatening risks associated with Androderm therapy, Actavis and/or its predecessors-in-interest failed to warn consumers, patients, and prescribing physicians.

329. At all times material hereto, despite actual knowledge of grave risks to consumers and patients of serious life- and limb-threatening cardiovascular and cerebrovascular injuries, and the presence of additional safety signals, Actavis and/or its predecessors-in-interest took no action to provide accurate, true, and correct information to consumers concerning the use of the Androderm product.

330. At all times material hereto, despite actual knowledge of grave risks to consumers and patients of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events, and the presence of additional safety signals, Actavis and/or its predecessors-in-interest took no action to provide accurate, true, and correct information to physicians concerning the prescription of the Androderm product.

331. Actavis and/or its predecessors-in-interest were reckless and wanton in their failure to provide prescribing physicians with appropriate warnings concerning the life- and limb-threatening cardiovascular and cerebrovascular events caused or increased in the risk of harm by the use of Androderm, about which Actavis and/or its predecessors-in-interest had actual knowledge.

332. Actavis and/or its predecessors-in-interest were reckless and wanton in their failure to provide consumers and patients with warnings concerning the life- and limb-threatening cardiovascular and cerebrovascular events caused or increased in the risk of harm by the use of Androderm, about which Actavis and/or its predecessors-in-interest -in-interest had actual knowledge.

333. Actavis and/or its predecessors-in-interest knew, contemplated, and intended that consumers and patients would reasonably and justifiably rely on the comprehensive medical information provided to them by Actavis and/or its predecessors-in-interest through patient

awareness and educational campaigns, and this reliance was, in fact, a focal point in the scheme by Actavis and/or its predecessors-in-interest to drive consumer demand for the Androderm product.

334. Actavis and/or its predecessors-in-interest knew, contemplated, and intended that consumers and patients would rely on the information provided to them by Actavis and/or its predecessors-in-interest concerning the Androderm product through comprehensive awareness and educational campaigns, which were undertaken for the purpose of fostering the belief that the Androderm product was approved for and was clinically indicated for the treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

335. Actavis and/or its predecessors-in-interest knew that the information they provided to consumers and patients promoted "off-label" product use and "label expansion," and that this information was false, deceptive, and misleading.

336. The willful, wanton, and reckless conduct of Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages.

337. The Plaintiff-husband would not have sought treatment for "Low T" nor would have administered Androderm had he been informed by Actavis and/or its predecessors-in-interest, as he should have been, of the information concerning cardiovascular and cerebrovascular risks, which was known to Actavis and/or its predecessors-in-interest at the time.

338. The Plaintiff-husband would not have sought treatment with Androderm had he been informed by Actavis and/or its predecessors-in-interest, as he should have been, that the clinical safety and efficacy profiles of this treatment were lacking, and that treatment of "Low T" with Androderm was neither approved nor clinically indicated.

339. The Plaintiff-husband would not have sought treatment with Androderm had he been informed by Actavis and/or its predecessors-in-interest, as he should have been, that Androderm was not approved for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

340. The Plaintiff-husband's prescribing physician would not have prescribed Androderm to his patient had he been informed by Actavis and/or its predecessors-in-interest that the FDA had not approved Androderm for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

341. The willful, wanton, and reckless conduct of Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages.

342. The willful, wanton, and reckless conduct of Actavis and/or its predecessors-in-interest caused the Plaintiff-wife's loss of consortium.

343. Accordingly, Actavis is liable to the Plaintiffs for punitive and exemplary damages, as set forth in the *ad damnum* clause.

COUNT IV—BREACH OF EXPRESS WARRANTY

344. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

345. Actavis and/or its predecessors-in-interest made statements, affirmations, and representations of fact concerning the Androderm product through its comprehensive consumer awareness and educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients, and end-users of the Androderm product that Androderm was clinically indicated for the treatment of "Low T."

346. Actavis and/or its predecessors-in-interest's statements, affirmations, and representations of fact concerning the Androderm product and it clinical use in the treatment of "Low T" that were intended to and did reach the Plaintiff-husband, and which formed a "basis of the bargain" for his decision to seek treatment for "Low T" and accept Androderm as an approved and clinically safe and effective treatment for "Low T."

347. Actavis and/or its predecessors-in-interest expressly warranted that Androderm was appropriate for the treatment of "Low T," including statements, affirmations, and representations on the Androderm website and via branded television commercials and advertising.

348. The Plaintiff-husband knew about and was aware of these representations made by Actavis and/or its predecessors-in-interest concerning Androderm, and these representations informed and guided his acceptance, use, and continued use of the Androderm product.

349. Actavis and/or its predecessors-in-interest expressly warranted that an appropriate indication for use of the Androderm product was to restore testosterone levels in consumers with "Low T."

350. Androderm did not conform to this express representation and warranty.

351. Specifically, Androderm was not an approved treatment for:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

352. The Plaintiff-husband reasonably and justifiably relied upon the representations, statements, or affirmations of fact of Actavis and/or its predecessors-in-interest in his choice to use and continue to use the Androderm product.

353. The Plaintiff-husband was unskilled in the research, design and manufacture of medical drugs, including Androderm, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of Actavis and/or its predecessors-in-interest in his choice to use the Androderm product.

354. Accordingly, Androderm did not comply with or conform to the representations, statements, or affirmations of fact made by Actavis and/or its predecessors-in-interest in terms of the express warranties made to consumers and patients, including the Plaintiff-husband.

355. The breach of the express warranty by Actavis and/or its predecessors-in-interest caused injury and damages to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

356. Accordingly, Actavis is liable to the Plaintiffs for their injuries, losses, and damages arising out of their breach of express warranty.

COUNT V—BREACH OF IMPLIED WARRANTY

357. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

358. At all times material hereto, Actavis and/or its predecessors-in-interest knew or had reason to know of the particular purpose for which users of the Androderm product were using Androderm, and that the users of Androderm were relying on the promotional and advertising materials of Actavis and/or its predecessors-in-interest in their selection of the product for that particular use.

359. Actavis and/or its predecessors-in-interest had reason to know that users of Androderm were using the product to treat "Low T" or age-related declines in testosterone levels or age-related symptoms in men, and that consumers and patients were reasonably and justifiably relying on the representations of Actavis and/or its predecessors-in-interest that Androderm was a treatment for "Low T."

360. Through aggressive physician detailing and promotion, Actavis and/or its predecessors-in-interest participated in the selection of Androderm by both prescribers and consumers as a treatment for "Low T."

361. At all times material hereto, Androderm did not have the requisite clinical safety or effectiveness profiles to be deemed fit for the particular purpose of treating "Low T."

362. At all times material hereto, the FDA had not approved the Androderm product for this particular purpose of use of treating "Low T" or age-related symptoms and age-related declines in testosterone levels in men.

363. Androderm did not conform to this implied warranty of fitness for the particular purpose of treating "Low T."

364. Androderm was not suitable for or approved by the FDA for the treatment of "Low T;" was neither safe nor effective in its clinical profiles for this use; and was not approved or indicated for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

365. Prior to the time that Androderm was used by the Plaintiff-husband, Actavis and/or its predecessors-in-interest impliedly warranted to the Plaintiff-husband and his

prescribing physician that Androderm was of merchantable quality and safe and fit for the use for which it was intended.

366. Specifically, Actavis and/or its predecessors-in-interest warranted to the Plaintiff-husband that its product was intended to treat a condition called "Low T" and that it was safe and fit for that use.

367. Actavis and/or its predecessors-in-interest failed to disclose that "Low T" is not a recognized medical condition and that Androderm was not FDA approved to treat "Low T."

368. The Plaintiff-husband was unskilled in the research, design, and manufacture of medical drugs, including Androderm, and reasonably and justifiably relied entirely on the skill, judgment and implied warranty of in using Androderm.

369. As a result, the Plaintiff-husband used Androderm as intended and warranted by Actavis and/or its predecessors-in-interest.

370. Androderm was neither safe for its intended use nor of merchantable quality, as warranted by Actavis and/or its predecessors-in-interest, in that Androderm had and continues to have dangerous propensities when used as intended, and will cause or increase the risk of harm of severe injuries to end-users.

371. The breach of the implied warranty of fitness for a particular purpose by Actavis and/or its predecessors-in-interest caused personal injury and damages to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

372. Accordingly, Actavis and/or its predecessors-in-interest are liable to the Plaintiff-husband for their injuries, losses, and damages arising out of the breach of implied warranty for a particular purpose.

373. Actavis and/or its predecessors-in-interest's breach of the implied warranty of merchantability caused personal injury to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

374. Accordingly, Actavis is liable to the Plaintiffs for their injuries, losses, and damages arising out of the breach of implied warranty of merchantability.

COUNT VI–FRAUD

375. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

376. Plaintiff herein pleads the elements of fraud with particularity, to include:

a. the knowingly false statements and misrepresentations of material fact made by Actavis and/or its predecessors-in-interest concerning the FDA-approved indications for clinical use of Androderm; the clinical safety and effectiveness profiles of Androderm; the clinical entities of primary and secondary hypogonadism which Androderm was FDA-approved to treat; and the definition of hypogonadism;

b. the knowledge on the part of Actavis and/or its predecessors-in-interest that these statements concerning Androderm and its clinical indications for use of the Androderm product were untrue;

c. the intent on the part of Actavis and/or its predecessors-in-interest to deceive consumers, including the Plaintiff-husband, concerning the Androderm product for the purpose of financial and economic gain;

d. the reasonable and justifiable reliance of the Plaintiff-husband on the fraudulent statements of Actavis and/or its predecessors-in-interest;

e. the resulting injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium suffered by the Plaintiff-wife, caused by the Plaintiff-husband's reasonable and justifiable reliance on these fraudulent statements and the willful lack of disclosure and fact suppression by Actavis and/or its predecessors-in-interest.

377. Actavis and/or its predecessors-in-interest undertook and had a duty to disclose all material facts relating to the use of Androderm to consumers and patients via its multi-platform comprehensive consumer awareness, educational, informational, and marketing formats and campaigns, including to the Plaintiff-husband.

378. Actavis and/or its predecessors-in-interest knew, understood, and contemplated that consumer belief in the clinical safety and effectiveness profiles of the Androderm product was pivotal to the sale, use, and demand for Androderm.

379. Actavis and/or its predecessors-in-interest additionally knew that consumers would otherwise believe that the promoted use of Androderm to treat "Low T" was an approved and indicated clinical use absent truthful statements to the contrary.

380. Actavis and/or its predecessors-in-interest had a duty to provide consumers with full, complete, accurate, and truthful information concerning the Androderm product, its FDA-approved spectrum of indications for clinical use, and the appropriate and medically sound definitions of hypogonadism and "Low T."

381. Actavis and/or its predecessors-in-interest knew that Androderm was not approved by the FDA for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

382. At all times material hereto, the FDA was unaware of any data to support these indications for the use of Androderm, and Actavis and/or its predecessors-in-interest were aware of the both the FDA's state of knowledge and the FDA-approved clinical uses for the Androderm product.

383. Nonetheless, Actavis and/or its predecessors-in-interest encouraged consumers to self-screen for these signs and symptoms via self-assessment questionnaires and "Low T" quizzes and clinical questions which solicited signs and symptoms of "Low T" to foster the false belief among consumers that they harbored a "disease" requiring testosterone replacement therapy with the Androderm product.

384. Actavis and/or its predecessors-in-interest engaged in fraudulent representations of material fact to consumers and patients, and willfully failed to disclose material facts to consumers and patients, including to the Plaintiff-husband, concerning the approved clinical indications for Androderm use; the clinical safety and effectiveness profiles of Androderm; the "off-label" use of Androderm and the "label expansion" that was occurring with the Androderm product; and the nature of "Low T" and the medical definition of hypogonadism.

385. Actavis and/or its predecessors-in-interest knew and understood that Androderm was being marketed and promoted to consumers, patients, and physicians, including the Plaintiff-husband and his prescribing physician, to treat age-related symptoms, including:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; and

g. bone strength or density abnormalities.

386. Actavis and/or its predecessors-in-interest knew and understood that it was necessary to generate and reinforce a belief amongst consumers and patients, including the Plaintiff-husband, which was knowingly false, deceptive, and misleading, that Androderm was an appropriate and FDA-approved treatment for "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

387. Actavis and/or its predecessors-in-interest specifically targeted male consumers over 50 years of age, knowing that at least 20% of this population manifested an age-relate decline in testosterone levels, and that many in this population would additionally and coincidently experience age-related symptoms as part of the *normal* aging process.

388. Actavis and/or its predecessors-in-interest advantaged the normal age-related decline in testosterone levels in the aging male population to create the illusion of an epidemic of

hypogonadism, claiming that millions of men suffered from a disease known as "Low T." This was false and misleading.

389. Actavis and/or its predecessors-in-interest advantaged the intentional ambiguity in the Androderm product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians. This ambiguity was additionally advantaged through the recruitment of "thought leaders," "key opinion leaders," and sponsored and funded researchers and research in testosterone replacement therapy, who promoted "off-label" Androderm use and "label expansion" through the medical literature and presentations.

390. This knowledge formed a basis for Androderm branding and marketing teams to design and execute various "Low T" consumer awareness and education campaigns, and to organize a concerted nationwide effort to encourage mass self-screening by consumers and encouraged demand for clinical laboratory testosterone testing crafted to lead consumers to a diagnosis of "Low T" and Androderm treatment.

391. Actavis and/or its predecessors-in-interest coupled this consumer self-screening campaign to an aggressive and pervasive physician detailing, promotional, and educational campaigns of misinformation, designed to achieve a confluence of consumer-driven demand for Androderm and increased "off-label" physician prescribing of the Androderm product.

392. Actavis and/or its predecessors-in-interest knew and understood that consumer attitudes and demand for the Androderm treatment were a key driver for Androderm's revenue stream, earnings, and market share, and that it was necessary, in order to drive product sales, to convince men that Androderm was an appropriate treatment modality for:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

393. The Androderm website was not constructed for the treatment of primary or secondary hypogonadism; rather, it specifically discussed "Low T" as the central and only diagnosis driving Androderm treatment by consumers and patients.

394. Actavis and/or its predecessors-in-interest knowingly, intentionally, and with fraudulent intent made false, misleading, and inaccurate representations of fact, and suppressed and failed to disclose material facts, concerning the following:

a. "Low T" was not and never has been an approved clinical indication for treatment with Androderm;

b. "Low T" is not a disease;

c. the definition of hypogonadism does not include the diagnosis of "Low T" or age-related decline in testosterone levels or age-related symptoms in men;

d. the diagnostic and clinically relevant criteria for the use of Androderm as a testosterone replacement therapy modality are specifically primary and secondary hypogonadism, and not "Low T," and the conditions of primary and secondary hypogonadism refer to specific pathologic conditions;

e. clinical safety and effectiveness profiles of Androderm as a treatment modality for "Low T" or age-related decline in testosterone levels or age-related symptoms in men are lacking;

f. clinical safety and effectiveness profiles for the use of Androderm in the treatment of conditions which do not fall under the rubric of hypogonadism are lacking;

g. the FDA-approved appropriate indications for the clinical use of Androderm do not include "Low T;"

h. the attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use testosterone, which occur through a spectrum of mechanisms known and described prior to the product launch of Androderm; and

i. the "mass, uncontrolled experiment" that Actavis and/or its predecessors-in-interest were performing on men being treated with Androderm for age-related declines in testosterone levels and age-related symptoms.

395. Actavis and/or its predecessors-in-interest had actual knowledge of the falsity of statements made to consumers and prescribers concerning Androderm, and willfully and knowingly failed to disclose, or to accurately, fully and truthfully state, that:

a. primary and secondary hypogonadism, and not "Low T" or age-related declines in testosterone levels or age-related symptoms in men, were the FDA-approved indications for the clinical use of Androderm;

b. the definition of hypogonadism is not synonymous with "Low T" or age-related declines in testosterone levels or age-related symptoms in men, and

that primary and secondary hypogonadism are caused by specific testicular or hypothalamic-pituitary-gonadal axis diseases and pathologic conditions;

c. "Low T" is not a diagnosis or condition warranting Androderm therapy, and in fact, "Low T" is an "off-label" clinical use for the Androderm product which was not approved by the FDA;

d. the diagnostic, clinically relevant, and medically appropriate criteria for the use of Androderm are not simply a low testosterone level and non-specific, age-related symptoms in men;

e. clinical safety and effectiveness profiles of Androderm for the treatment of "Low T," and the long-term use of testosterone replacement therapy to treat age-related declines in testosterone levels or age-related symptoms in men are lacking;

f. clinical safety and effectiveness profiles for the use of Androderm in the treatment of "Low T" are unsupported by any long-term, appropriately blinded, placebo-controlled, adequately powered, independent clinical study;

g. the attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of Androderm.

396. Actavis and/or its predecessors-in-interest knew that:

a. the consumer awareness and consumer-directed multi-platform comprehensive educational, informational, and "Low T" screening

questionnaires and interactive campaigns; and the drive to provoke, stimulate, and increase a consumer driven demand for "off-label" use of Androderm to include the treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms in men; and

b. the purported diagnostic criteria offered to consumers and non-specific diagnostic criteria crafted to lead men to self-diagnose potential "Low T" and to thereafter seek further evaluation and eventual treatment with Androderm; and

c. the informational campaigns touting Androderm as an accepted and approved treatment for "Low T;"

Would thereby create a belief among consumers and prescribers, which Actavis and/or its predecessors-in-interest knew to be false, inaccurate, and misleading, that:

a. Androderm was an FDA-approved, appropriate, and accepted treatment modality for "Low T" or age-related declines in testosterone levels and age-related symptoms in men; and

b. "Low T" was a variant of hypogonadism, and was therefore an indication for Androderm therapy; and

c. Androderm had known and favorable profiles of clinical safety and effectiveness for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms; and

d. Androderm carried no known risk of serious adverse life- or limb-threatening cardiovascular or cerebrovascular events.

397. Actavis and/or its predecessors-in-interest intended that the aforementioned material falsehoods, fraudulent and deceptive representations, and willful failures to disclose be relied and acted upon by consumers, patients, and prescribers in order to increase Androderm product demand, corporate revenues and profits, and the market share of Androderm in the testosterone replacement therapy space.

398. Actavis and/or its predecessors-in-interest further knew, understood, and intended, that consumer and prescriber reliance on these fraudulent representations and lack of disclosures would cause or increase the risk of harm of serious adverse life- and limb-threatening injury among Androderm product users, including the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

399. Actavis and/or its predecessors-in-interest knew and understood that it was exposing, and attempting to further expose, millions of men (20% of the male population over 50 years of age) to the risks for Androderm treatment for "Low T" for which there was no demonstrable profile of clinical safety or effectiveness, and more fundamentally, no approved indication for use. This was "a mass, uncontrolled experiment" conducted by Actavis and/or its predecessors-in-interest.

400. The Plaintiff-husband reasonably and justifiably relied to his detriment upon these fraudulent and materially false, deceptive, and misleading representations, and would not have otherwise sought treatment for "Low T" or administered Androderm had the fraudulent representations not been made to him or if he had not been induced to select treatment for "Low T" based upon these fraudulent statements and intentional failures to disclose by Actavis and/or its predecessors-in-interest t.

401. Actavis and/or its predecessors-in-interest intentionally and willfully disseminated materially false and fraudulent statements to consumers and patients, including the Plaintiff-husband, and placed a product within the stream of interstate commerce substantially for "off-label" use and "label expansion," as a commercial enterprise for financial and economic benefit at the expense of public health and public safety, including the safety and well-being of the Plaintiff-husband.

402. Actavis and/or its predecessors-in-interest knew that testosterone replacement preparations, including Androderm:

a. were dangerous in their effects on blood coagulation and viscosity, estradiol levels, and the effects upon HDL and LDL levels;

b. lacked long-term clinical safety and effectiveness profiles;

c. were not approved by the FDA for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men;

d. were being aggressively detailed to physicians for "off-label" usage and "label expansion" without appropriate warnings or information to prescribing physicians concerning the FDA-approved indications for clinical use;

e. were being marketed and promoted to consumers and patients via comprehensive awareness and educational campaigns and mass-screening questionnaires and interactive websites soliciting Personal Health Information (PHI); and

f. did not inform consumers, patients, or physicians concerning the full spectrum and severity of serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks attendant with testosterone therapy.

403. Actavis and/or its predecessors-in-interest fraudulently concealed or misrepresented these material facts.

404. Actavis and/or its predecessors-in-interest knew and understood, throughout Androderm product lifecycle including at the time of product launch in or about 1995, that declines in testosterone levels are a normal component of the male aging process, and that returning testosterone levels "physiologic" levels to treat the diagnosis of "Low T" in aging men would foreseeably and predictably cause or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

405. Actavis and/or its predecessors-in-interest knew and understood that a decline in testosterone levels is a component of the male aging process, and that through aggressive direct-to-consumer comprehensive awareness and promotional campaigns, including branded and unbranded consumer education, advertising, and medical information campaigns, all of which portrayed "Low T" as treatable "disease," that there would be an increasing demand for the treatment of "Low T" by middle-aged and elderly men with the Androderm product.

406. Actavis and/or its predecessors-in-interest knew and understood that Androderm's revenue stream and bottom-line earnings would be favorably affected by the interface of

increased consumer and patient product demand, driven and stimulated by the role of Actavis and/or its predecessors-in-interest in creating and/or offering:

a. false and misleading direct-to-consumer renditions of comprehensive medical and diagnostic information concerning "Low T" and hypogonadism and the indications for clinical use of Androderm;

b. false and misleading Androderm product testimonials and endorsements;

c. information designed to identify signs and symptoms purportedly diagnostic of a "disease," "Low T," treatable with Androderm;

d. proffered differential diagnoses for signs and symptom complexes for which Androderm is not an approved treatment option;

e. false and misleading information concerning testosterone therapy, its clinical usefulness to treat age-related declines in testosterone levels and age-related symptoms in men, and its clinical safety and effectiveness profiles;

f. the solicitation of Protected Health Information (PHI) to further drive consumer demand via direct-to-patient communication and "Low T" treatment encouragement from and by Actavis and/or its predecessors-in-interest;

g. recommendations for testosterone laboratory testing;

h. assistance with medical insurance and third-party payer coverage for Androderm prescriptions;

i. physicians who are sponsored speakers, "thought-leaders," "key opinion leaders," and consultants paid or supported by Actavis and/or its predecessors-in-interest; and

j. prescription refill reminders.

407. The aggressive promotional and detailing drives by Actavis and/or its predecessors-in-interest were designed and executed to increase "off-label" prescription writing habits and "label expansion" by physicians.

408. Actavis and/or its predecessors-in-interest knowingly sought to invent and reinforce a "disease" known as "Low T," and thereafter targeted the 20 million men middle-aged men whom Actavis and/or its predecessors-in-interest knew would experience declines in testosterone levels and non-specific signs and symptoms of the aging process, to fraudulently induce them to become Androderm users.

409. The fraudulent conduct of Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium damages of the Plaintiff-wife.

410. Accordingly, Plaintiffs are entitled to punitive and exemplary damages against Actavis, as set forth in the *ad damnum* clause, arising out of the fraudulent conduct of Actavis and/or its predecessors-in-interest, as stated with particularity herein.

COUNT VII—NEGLIGENT MISPREPRESENTATION

411. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

412. Plaintiff herein pleads the elements of negligent misrepresentation, to include:

a. The statements and representations of Actavis and/or its predecessors-in-interest of material fact to consumers and patients concerning the FDA-approved indications for clinical use of Androderm; and the clinical safety and effectiveness profiles of Androderm; and the signs and symptoms which Androderm was FDA-approved to treat, which Actavis and/or its predecessors-in-interest should have known were false;

b. The misrepresentation to consumers and patients by Actavis and/or its predecessors-in-interest of the definition of hypogonadism and the distinction between "Low T" and hypogonadism, which Actavis and/or its predecessors-in-interest should have known were false and misleading;

c. the failure by Actavis and/or its predecessors-in-interest to know that the aforementioned statements of material fact concerning its Androderm product were false and misleading;

d. the justifiable and reasonable reliance of the Plaintiff-husband on the negligent misrepresentations of Actavis and/or its predecessors-in-interest;

e. the resulting injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium suffered by the Plaintiff-wife, caused by the Plaintiff-husband's reasonable and justifiable reliance on these negligent misrepresentations, to his detriment, through his use of the Androderm product.

413. Actavis and/or its predecessors-in-interest had a duty to disclose all material facts relating to the use of Androderm to consumers and patients via its multi-platform comprehensive

consumer awareness, educational, informational, and marketing formats and campaigns, including to the Plaintiff-husband.

414. Actavis and/or its predecessors-in-interest should have known and understood that consumer acceptance of and belief in the clinical safety and effectiveness profiles of the Androderm product were central to the sale, use, demand for, and physician prescribing habits for Androderm.

415. Actavis and/or its predecessors-in-interest had a duty to provide consumers and patients with full, complete, accurate, and truthful information concerning the Androderm product, including the product's FDA-approved spectrum of indications for clinical use; and appropriate and medically sound and accurate definitions of hypogonadism and "Low T;" and the clinical safety and effectiveness profiles of Androderm.

416. Actavis and/or its predecessors-in-interest should have known that Androderm was not approved by the FDA for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

417. At all times material hereto, Actavis and/or its predecessors-in-interest knew, or should have known, that the FDA was unaware of any data to support these indications for the clinical use of Androderm.

418. At all times material hereto, and since the time of FDA approval of the Androderm product, Actavis and/or its predecessors-in-interest knew or should have known that the FDA had not approved Androderm as therapy:

a. to improve mood;

b. to increase sexual interest;

c. to restore erectile function;

d. to increase muscle mass; or

e. to increase strength of bones.

419. Nonetheless, Actavis and/or its predecessors-in-interest encouraged consumers to self-screen for these signs and symptoms via questionnaires and selected and interactive quizzes and clinical questions, in order to foster the false belief among consumers that they harbored a "disease" requiring testosterone replacement therapy with Androderm.

420. Actavis and/or its predecessors-in-interest should have, but failed, to disclose material facts to consumers, including the Plaintiff-husband, concerning the approved indications for clinical use of Androderm; the lack of clinical safety and effectiveness profiles of the Androderm product; the "off-label" use of Androderm and the "label expansion" that was occurring with the Androderm product; the true nature of the condition known as "Low T;" and the correct medical definition of hypogonadism.

421. Actavis and/or its predecessors-in-interest should have known that Androderm was being marketed and promoted to consumers and patients, including the Plaintiff-husband, to treat age-related symptoms, including:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

422. Actavis and/or its predecessors-in-interest should have known that:

a. "Low T" is not an approved indication for clinical treatment with Androderm;

b. "Low T" or age-related declines in testosterone levels and age-related symptoms in men is not the same medical entity as primary or secondary hypogonadism, which were the FDA-approved indications for Androderm use;

c. the diagnostic and clinically relevant criteria for the use of Androderm as a testosterone replacement treatment modality do not include age-related declines in testosterone levels and age-related symptoms;

d. clinical safety and effectiveness profiles of Androderm as a treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms were lacking;

e. clinical safety and effectiveness profiles for the use of Androderm in the treatment of conditions which do not fall under the rubric of hypogonadism were untested and lacking, and that they were conducting "a mass, uncontrolled experiment" through its marketing and promotion of Androderm to treat "Low T;"

f. the FDA-approved indications for the clinical use of Androderm did not include "Low T;" and

g. there were and are attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of testosterone-containing products, including Androderm, which occur through a spectrum of metabolic mechanisms which should have been known to Actavis and/or its predecessors-in-interest prior to the product launch of Androderm in or about 1995.

423. Actavis and/or its predecessors-in-interest should have known that:

a. primary and secondary hypogonadism, and not "Low T" or age-related declines in testosterone levels or age-related symptoms in men, are the appropriate FDA-approved indications for the clinical use for Androderm;

b. the definition of hypogonadism is not synonymous with "Low T" or age-related declines in testosterone levels or age-related symptoms, and that

primary and secondary hypogonadism are caused by specific testicular or hypothalamic-pituitary-gonadal axis diseases or conditions;

c. "Low T" is not a diagnosis or condition warranting Androderm therapy, and in fact, "Low T" is an "off-label" indication for use or "label expansion" for the Androderm product;

d. "Low T" is not a disease;

e. the diagnostic, clinically relevant, and medically appropriate criteria for the use of Androderm are not simply a low testosterone level and non-specific, age-related symptoms in men;

f. clinical safety and effectiveness profiles of Androderm for the treatment of "Low T" and the long-term use of testosterone replacement therapy to treat age-related declines in testosterone or age-related symptoms in men are lacking;

g. clinical safety and effectiveness profiles for the use of Androderm in the treatment of "Low T" were unsupported by any long-term, appropriately blinded, placebo-controlled, sufficiently powered, and independent clinical studies; and

h. there are attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of Androderm.

424. Actavis and/or its predecessors-in-interest should have known that:

a. the comprehensive consumer awareness and consumer-directed multi-platform educational, informational, and "Low T" screening questionnaires and interactive campaigns; and

b. the concerted drive to provoke, stimulate, and increase a consumer driven demand for "off-label" clinical use of the Androderm product to include the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men; and

c. the purported diagnostic criteria for "Low T" offered to consumers and the encouragement to seek testosterone level testing which were crafted to lead men to self-diagnose "Low T" and to seek medical diagnosis and treatment with Androderm; and

d. the informational campaigns touting Androderm as an accepted and approved treatment for "Low T;"

Would thereby create a belief among consumers, which Actavis and/or its predecessors-in-interest should have known to be false and inaccurate that:

a. Androderm was an FDA-approved, appropriate, and accepted treatment modality for "Low T" or age-related declines in testosterone levels or age-related symptoms in men; and

b. "Low T" was a variant of hypogonadism and was therefore an indication for Androderm therapy; and

c. Androderm had a known and favorable profiles of clinical safety and effectiveness for the treatment of "Low T" or age-related declines in testosterone and age-related symptoms in men; and

d. Androderm carried no known risk of serious adverse life- and limb-threatening cardiovascular or cerebrovascular events.

425. Actavis and/or its predecessors-in-interest should have known that the aforementioned misrepresentations were material to consumer's and patient's use of the Androderm product, and would be reasonably and justifiably relied and acted upon by consumers and patients who would thereby demand treatment for "Low T" with the Androderm product.

426. Actavis and/or its predecessors-in-interest should have known that samples and discount and rebate coupons would drive consumer demand for treatment with Androderm, and that the "off-label" promotion and detailing to physicians would increase unwarranted and unjustified Androderm consumer and patient use.

427. Actavis and/or its predecessors-in-interest should have known that consumer reliance on these negligent misrepresentations and failures to disclosure would cause or increase the risk of harm of serious adverse life-and limb-threatening cardiovascular and cerebrovascular events among Androderm users, including the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

428. Actavis and/or its predecessors-in-interest should have known that they were exposing, and attempting to further expose, millions of men to the unreasonable risks of Androderm treatment for "Low T," because Androderm had no demonstrable profile of clinical safety or effectiveness in the treatment of "Low T," and more fundamentally, because "Low T" or age-related declines in testosterone level and age-related symptoms were not FDA-approved indications for Androderm use. Actavis and/or its predecessors-in-interest should have known that they were conducting "a mass, uncontrolled experiment" with the Androderm product, and thereby misrepresented the nature of Androderm therapy for "Low T."

429. The Plaintiff-husband reasonably and justifiably relied to his detriment upon these negligent misrepresentations and failures to disclose material facts, and would not have otherwise sought treatment for "Low T" or administered or continued to administer Androderm to himself had these misrepresentations and failures of disclosure not been made to him.

430. Actavis and/or its predecessors-in-interest negligently disseminated materially false statements to consumers and patients, and negligently placed a product within the stream of interstate commerce substantially for "off-label" use and "label expansion," as a commercial enterprise for the contemplated financial and economic benefit to Actavis and/or its predecessors-in-interest at the expense of public health and public safety, including the safety and well-being of the Plaintiff-husband.

431. Actavis and/or its predecessors-in-interest should have known that testosterone preparations, including Androderm:

a. were dangerous in their effects on blood coagulation and viscosity, estradiol levels, and effects upon HDL and LDL levels;

b. lacked long-term clinical safety and effectiveness profiles;

c. were not approved by the FDA for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men;

d. were being aggressively detailed to physicians for "off-label" usage and "label expansion" without appropriate warnings and without appropriate information to prescribing physicians concerning the FDA-approved indications for clinical use;

e. were being marketed and promoted to consumers via comprehensive awareness and educational campaigns and mass-screening questionnaires and interactive websites with inadequate and false information included; and

f. did not carry information for consumers or patients concerning the full spectrum of serious adverse life- and limb-threatening cardiovascular and cerebrovascular risks attendant with testosterone therapy.

432. Actavis and/or its predecessors-in-interest should have known throughout Androderm's product lifecycle, including at the time of product launch in or about 1995, that declines in testosterone levels is a component of the *normal* male aging process, and that returning testosterone levels to "physiologic" levels to treat the diagnosis of "Low T" in aging men would foreseeably and predictably cause or increase the risk of harm of adverse serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

433. Actavis and/or its predecessors-in-interest should have known that a decline in testosterone levels is component of the *normal* male aging process, and that through aggressive direct-to-consumer advertising, including branded and unbranded consumer education and medical information campaigns, all of and portrayed "Low T" as treatable "disease," there would

be an increasing demand for treatment of "Low T" by middle-aged and elderly men with the Androderm product.

434. Actavis and/or its predecessors-in-interest negligently invented, reinforced, and represented to consumers and the public concerning a "disease" known as "Low T," and targeted the 20 million men middle-aged men whom Actavis and/or its predecessors-in-interest knew would experience *normal* declines in testosterone levels and symptoms of the aging process to induce them through this presentation to seek treatment with Androderm.

435. The negligent misrepresentations and failures to disclose on the part of Actavis and/or its predecessors-in-interest caused or increased the risk of harm of the injuries suffered by the Plaintiff-husband, and the derivative loss of consortium of the Plaintiff-wife.

436. Accordingly, Actavis is liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT VIII—DECEPTIVE TRADE PRACTICES

437. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

438. Actavis and/or its predecessors-in-interest represented to the Plaintiff-husband, through multi-platform marketing and promotions that Androderm had sponsorship, approval, characteristics, uses, and benefits that the product, in fact, did not have.

439. Actavis and/or its predecessors-in-interest represented through word and deed that Androderm was approved by the FDA to treat "Low T." This was false, misleading, and deceptive.

440. Actavis and/or its predecessors-in-interest represented through word and deed that Androderm was clinically indicated for use to treat "Low T." This was false, misleading, and deceptive.

441. Actavis and/or its predecessors-in-interest represented through word and deed that Androderm was of proven clinical benefit in the treatment of "Low T." This was false, misleading, and deceptive.

442. Plaintiff-husband reasonably and justifiably relied to his detriment upon these materially false, deceptive, and misleading representations, and would not have otherwise sought treatment for "Low T" or administered Androderm had these representations not been made to him.

443. Accordingly, Actavis and/or its predecessors-in-interest is liable to the Plaintiff husband for their unfair trade practices, which caused the Plaintiff-husband to use the Androderm product and which increased the risk of harm of his injury.

444. Plaintiffs claim all elements of damages recoverable against Actavis for its deceptive trade practices.

COUNT IX—LOSS OF CONSORTIUM

445. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

446. Plaintiff-wife herein brings this derivative loss of consortium claim arising out of the injuries caused by Actavis and/or its predecessors-in-interest to her husband and claims entitlement to damages in her own right.

447. Because of the injuries suffered by her husband, Plaintiff-wife has experienced the loss of the company, society, cooperation, guidance, and companionship of her husband.

448. Accordingly, Actavis is liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiff-wife, in her own right, for the derivative injuries, losses, and damages she has suffered due to her husband's injuries and damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants as follows:

a. General damages in a sum in excess of the jurisdictional minimum of this Court;

b. Medical, incidental, and hospital expenses according to proof;

c. Pre-judgment and post-judgment interest as provided by law;

d. Full refund of all purchase costs Plaintiff paid for testosterone;

e. Compensatory damages in excess of the jurisdictional minimum of this Court;

f. Consequential damages in excess of the jurisdictional minimum of this Court, including loss of consortium damages on behalf of the Plaintiff-wife;

g. Punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

h. Attorneys' fees, expenses, and costs of this action; and,

i. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Respectfully submitted,

/s/*Mark A. Hoffman*
Mark A. Hoffman, Esquire
ROSS FELLER CASEY, LLP
One Liberty Place
1650 Market Street
Philadelphia, Pennsylvania 19103
Telephone: 215-574-2000
Facsimile: 215-574-3080
Email: mhoffman@rossfellercasey.com